



Green Ribbon Science Panel Meeting

April 23 - 24, 2019 – Sacramento, California

Meeting Materials can be found at:

https://dtsc.ca.gov/SCP/GRSP/April_23-24_2019.cfm



Department of Toxic Substances Control



CalEPA



Safer Consumer Products Program Update

Green Ribbon Science Panel April 23, 2019

Karl Palmer, Acting Deputy Director
Safer Products and Workplaces Program



Department of Toxic Substances Control



CalEPA



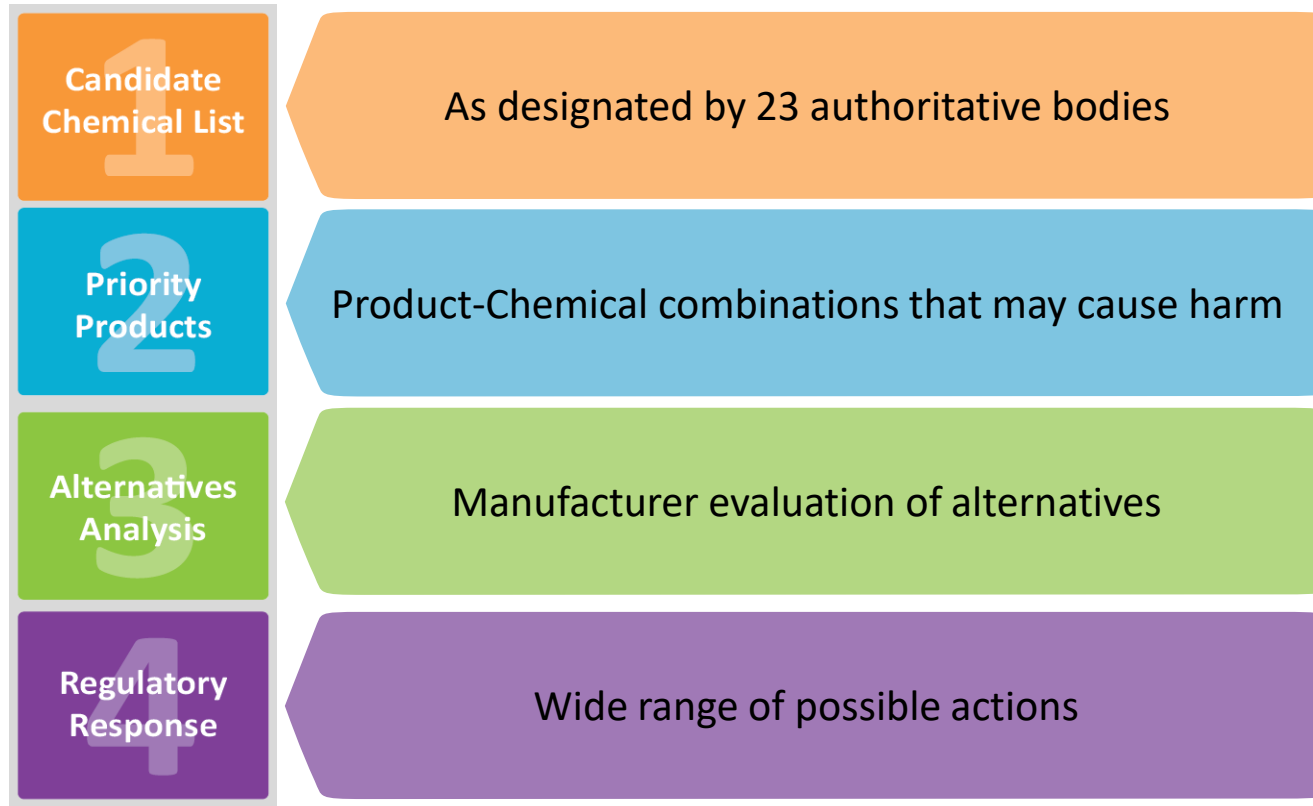
The Three Pillars of the SCP Program

Build Capacity

Lead the Way

Execute

Safer Consumer Products Framework



CC List Update

- 7 New CCs (not exempted), relating to Nitrobenzenes and Other Industrial Chemicals
- 10 updates to CC's already on the list

Chemical Name	CAS RN	Authoritative List	HT	In DB?	Date Added to CC List
4-Chloronitrobenzene	100-005	IARC 2B	Cancer	No	2018 Q4
1,4-Dichloro-2-nitrobenzene	89-61-2	IARC 2B	Cancer	No	2018 Q4
2-Chloronitrobenzene	88-73-3	IARC 2B	Cancer	No	2018 Q4
2,4-Dichloro-1-nitrobenzene	611-06-3	IARC 2B	Cancer	No	2018 Q4
para-Nitroanisole	100-17-4	IARC 2B	Cancer	No	2018 Q4
2-Amino-4-chlorophenol	95-85-2	IARC 2B	Cancer	No	2018 Q4
ortho-Phenylenediamine dihydrochloride	615-28-1	IARC 2B	Cancer	No	2018 Q4
N-Nitrosohexamethyleneimine	932-83-2	Prop 65	Cancer	No	2018 Q4
Bevacizumab	216974-75-3	Prop 65	Developmental, female	No	2019 Q1



The 2018-2020 Priority Products Work Plan



- Beauty, Personal Care, and Hygiene
- Cleaning Products
- Household, School, and Workplace Furnishing and Décor
- Building Products and Materials Used in Construction and Renovation
- Consumable Office, School and Business Supplies
- Lead-Acid Batteries
- Food Packaging



Priority Product Selection and Listing

1. Children's foam-padded sleeping products with TDCPP or TCEP flame retardants

- Listed July, 2017
- No PP Notifications received; an indicator that manufacturers eliminated use of these FRs?
- Sampling and analysis conducted by SCP
- DTSC January 2019 report findings: All 21 products tested were compliant
- Suggests shift away from FRs and the CoCs



Priority Product Selection and Listing

2. Spray Polyurethane Foam Systems with unreacted MDI

- Listed July, 2018
- December 2018, DTSC rejected American Chemistry Council's informal dispute requests
- February 2019, DTSC denied appeal by ACC to Director
- SCP working with ACC and manufacturers on notifications due April 26, 2019
- Preliminary Alternatives Analyses due to DTSC August 2019



Priority Product Selection and Listing

3. Paint or Varnish Strippers Containing Methylene Chloride

- Listed January 1, 2019
- 10 Manufacturers submitted PP Notifications, covering over 40 specific products
- Preliminary AAs due to DTSC end of September, 2019
- SCP working with Responsible Entities to ensure clarity on CA regulatory requirements in light of US EPA action under TSCA



Priority Product Selection and Listing

4. Laundry Detergents containing Nonylphenol Ethoxylates

- External Scientific Peer Review (ESPR) complete
- Public Notice for listing regulations - Summer 2019

5. Carpets and Rugs containing PFAS

- Made modifications of Profile based on GRSP input at last meeting
- Currently under ESPR
- Public Notice for listing regulations - Summer 2019



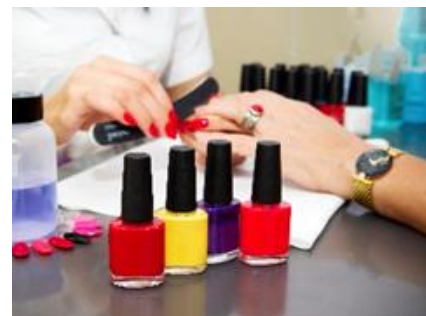
Priority Product Selection and Listing

6. Paint and Varnish Strippers and Graffiti Removers Containing N-methylpyrrolidone

- Submitted for ESPR
- Public Notice for listing regulations – Summer/Fall 2019

7. Nail Products Containing Toluene

- Public comments on product-chemical profile closed April 1, 2019
- SCP evaluating comments
- ESPR – Summer 2019
- Rulemaking – Fall 2019



Priority Product Selection and Listing

8. Zinc in Tires petition

- SCP requested supplemental information from petitioners
- Information due to DTSC this week

9. Lead Acid Batteries

- SCP continuing evaluation for potential for Priority Product listing



Key Milestones for 2019

- Two PPs' Preliminary Alternatives Analyses
- Four Proposed Priority Products in rulemaking
- Public workshops for new proposed Priority Products
- Decision on Zinc in Tires Petition
- Decision on Lead Acid Batteries



Additional Information Collection

- Nail Products Sampling and Analysis
- Nail Products Information Call-in
- Public workshop held March 13th for Nail Products Containing Toluene



Alternatives Analysis

■ External

- Alternatives Analysis Webinar, February 7th
 - *Focus on compliance with notifications and first stages of AA.*
- AA Fact Sheets:
 - [Introduction to the Alternatives Analysis Process](#)
 - [Alternatives Analysis Reporting Options](#)
 - [Notifications in Lieu of Alternatives Analysis](#)
- [Preliminary Alternatives Analysis Report Template, version 1.1](#) [March 2019]



Alternatives Analysis

■ External (continued)

- Assigned individual staff to each Responsible Entity
- Working with trade associations for Paint Strippers and SPF to facilitate process
- Clarifying regulatory requirements for Paint Strippers not covered by US EPA TSCA actions
- Preparing AA Examples Analysis for publication
- Posted links to previously published AAs and AA resources

■ Internal

- Planning for AA reviews
- Added staff
- Training and attendance at relevant meetings



2nd International Symposium on Alternatives Assessment: Building the Field

California Environmental Protection Agency (CalEPA)

Sacramento, California | November 1-2, 2018



<https://www.saferalternatives.org/>

Building capacity...

SCP hired seven new staff!!!

Will be hiring another Environmental Scientist and Toxicologist



Potential Legislative Action

- SB 392 (Allen) proposes several changes that would affect the SCP Program:
 - Would add various lists to the Candidate Chemicals list (fragrance allergens, asthmagens, CA biomonitoring's Designated Chemicals list, endocrine disruptors)
 - Would grant DTSC additional authority to obtain product ingredient information from manufacturers and suppliers
 - Would allow, if certain conditions are met, DTSC to utilize existing Alternatives Analyses to issue Regulatory Responses
 - Would add requirements to the Priority Product Work Plan to identify specific timelines and meet specified output goals



Strategic Planning...

■ SCP Finalized Program Strategic Plan

- 5 High Level Goals
 - *Objectives*
 - *Key Performance Indicators*
 - *Tactics*
- Strategic Stakeholder Engagement
- Program Workload Coordination
- Project Management
- Motivated and Innovative Teams
- Fiscal Planning and Management



Thank you

Contact me

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SCP home page

<http://www.dtsc.ca.gov/SCP>

CalSAFER

<http://calsafer.dtsc.ca.gov>

Candidate Chemical List

Product Listings/Rulemaking/

Petitions/ Technical documents

eList

<http://bit.ly/scpupdates>





Public Comments

Submit your comments to

SaferConsumerProducts@dtsc.ca.gov



Department of Toxic Substances Control



CalEPA



Establishing an Alternatives Analysis Threshold for Priority Products

Green Ribbon Science Panel
April 23, 2019

André Algazi
Chemical and Product Evaluation Team



Department of Toxic Substances Control



CalEPA

Outline

1. What is the Alternatives Analysis Threshold (AAT)?
2. When might DTSC set an AAT?
3. AAT for Chemicals of Concern present as contaminants
4. Policy considerations when setting an AAT
5. Questions for the panel



What is the AAT?

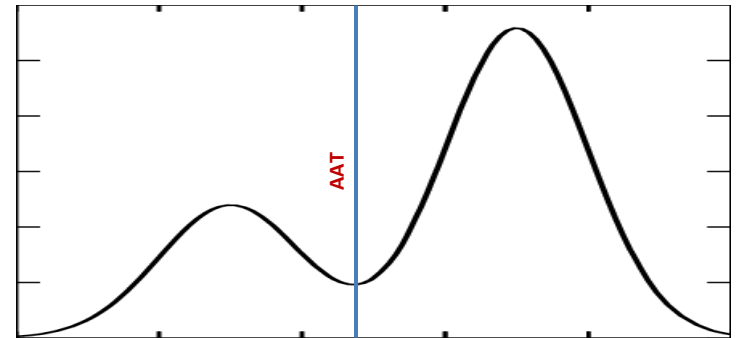
- A specified concentration of a Chemical of Concern in a Priority Product
- Set by DTSC in product listing regulations
- Exempts responsible entities whose PP contains the Chemical of Concern at concentrations below it from Alternatives Analysis
 - But... the RE must notify and provide supporting info
- At DTSC's discretion whether to set an AAT and at what level

25



When might DTSC specify an AAT?

- Most likely when distribution of concentrations of the Chemical of Concern is bimodal, due to:
 - Best practice vs. standard practices
 - Intentionally-added vs. contaminant
 - The CoC is used in similar products for different purposes (and at different concentrations)
 - Other?



AAT for contaminants

- For a Chemical of Concern that is a contaminant, the AAT must be set at or above the Practical Quantitation Limit (PQL)
“... the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.”
- DTSC specifies the PQL in the Priority Product listing regulations
- The PQL is:
 - Practical (DTSC cannot enforce compliance with levels that can't reliably be quantified)
 - Not based on risk
 - Often not straightforward to determine



Policy considerations

- DTSC might opt to set an AAT – and exempt some REs from conducting an AA – for several reasons:
 - To exempt products with *De minimis* concentrations. Products from some manufacturers' may contain a Chemical of Concern at higher concentrations, while those from other manufacturers contain concentrations well below levels of concern
 - To drive “laggards” to implement the best practices of the “leaders” for lowering the concentration of the Chemical of Concern
 - To focus on functional uses where exposure potential is highest
 - Other?



OEHHA's Safe Use Determination (SUD) Process

Green Ribbon Science Panel Meeting

April 23, 2019

Martha Sandy, Ph.D., M.P.H.

Office of Environmental Health Hazard Assessment
California Environmental Protection Agency



OEHHA
SCIENCE FOR A HEALTHY CALIFORNIA



Proposition 65: The Safe Drinking Water and Toxic Enforcement Act of 1986

- Requires California to publish a **list of carcinogens and reproductive toxicants**
- Does **not ban or restrict the use of a listed chemical**
- Applies to businesses with 10 or more employees – does not apply to governmental entities.
 - Must **warn the public of significant exposures**
 - Are **prohibited from discharging significant amounts of listed chemicals into sources of drinking water**

Significant exposures are those above the Safe Harbor Level, defined as follows:

- For Carcinogens: **No Significant Risk Levels (NSRLs)**
The daily intake level calculated to result in one excess case of cancer in a population of 100,000 exposed individuals
- For Reproductive and Developmental Toxicants: **Maximum Allowable Dose Levels (MADLs)**
The intake level having no observable effect (NOEL), divided by 1,000

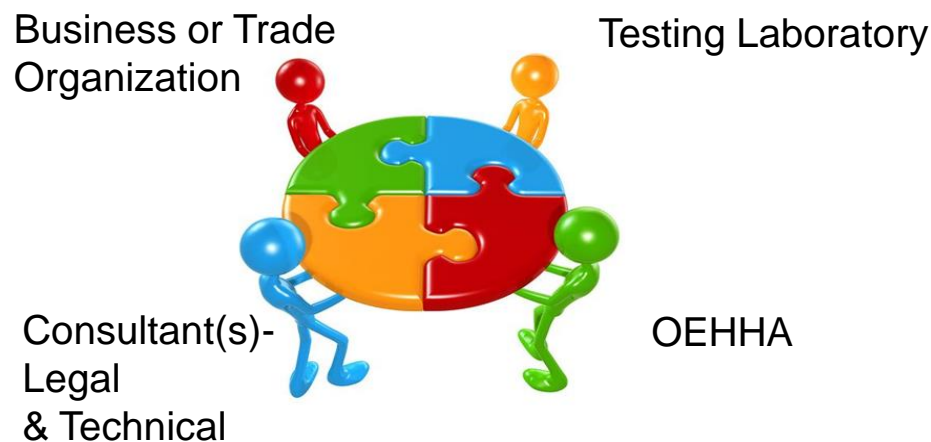


What is a Safe Use Determination (SUD) under Proposition 65?

- A written statement issued by OEHHA to a business or trade group
- A **determination that exposure** to (or discharge of) a Proposition 65 listed chemical, resulting from specific business actions or the average use of a specific product, **is not significant** and thus no warning is required



The SUD Process: Rigorous, DATA-DRIVEN, and Collaborative



The SUD Process:

The Requester determines the scope of the SUD request and gathers the data and information necessary to support the request

The Request is submitted to **OEHHA**, and includes a complete statement of all relevant facts, data and information

OEHHA reviews Request

*Note: **OEHHA** may request additional information**



*Requests for additional information typically involve scope (clarification) or data (data needed for evaluation and/or clarification as to how data were obtained).

OEHHA provides written acceptance / rejection of Request

***OEHHA** provides a cost estimate*

Public comment period (with public hearing if requested)

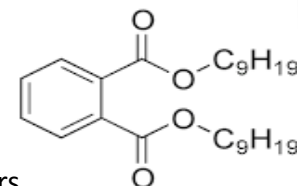
OEHHA reviews all materials and conducts exposure assessment

OEHHA issues SUD or takes other action

***OEHHA** can decline to issue a SUD, issue an informational letter, or issue an Interpretive Guideline*



SUD request for DINP in vinyl flooring products



From the Request

- Products are non-textile flooring materials consisting of polyvinyl chloride (PVC, vinyl), pigments, plasticizers (such as **DINP**), fillers (e.g., limestone), extenders, and stabilizers to protect against heat and light deterioration
- Four product categories: heterogeneous sheets, homogeneous sheets, vinyl tile, and vinyl composition tile
- **DINP** content in the four product categories included in the request ranges from **<1% to 22% by weight**

Chemical-specific factors

- Semi-volatile
- Absorption through the skin, GI tract, respiratory tract

Product-specific factors

- Used in homes, offices, and other settings

Exposure pathways

○ Professional Installers

- *Dermal absorption via direct contact with vinyl flooring products*
- *Incidental ingestion via hand-to-mouth contact*
[Inhalation is considered negligible, due to the slow rate of volatilization during the installation period]

○ Residents

- *Dermal absorption via direct contact with vinyl flooring products*
- *Incidental ingestion via hand-to-mouth contact*
- *Inhalation*



SUD Request for DINP in vinyl flooring (NSRL is 146 µg/day)

OEHHA conducted screening-level exposure analyses to derive upper-end estimates of DINP exposure

Professional Installers:

151 µg/day

Estimated
for flooring
containing
9% DINP
by weight

SUD issued
for products
containing
8.7% DINP
by weight, or
less

Table 2. Parameters used in and results of the OEHHA analysis of DINP exposures during installation of vinyl flooring products containing 9% DINP

Parameter	Unit	Value	Basis
Dermal absorption			
A. Hand (palmar surface) DINP loading	µg/day	278	= (139 µg/hand) x (two hands), maximum, measured @ 45 tiles, NRF (2014)
B. Human dermal absorption coefficient	unitless	0.15%	McKee <i>et al.</i> (2002); Scott <i>et al.</i> (1987) (see below)
C. Dermal dose	µg/day	0.4	= A x B
Hand-to-Mouth (HTM) ingestion			
D. HTM fingertip DINP loading	µg/event	51.9	Calculated by OEHHA based on wipe data from NRF, see text
E. HTM transfer efficiency	unitless	50%	OEHHA (2008)
F. HTM contact frequency	events/hr	2.28	Calculated by OEHHA based on Gorman Ng <i>et al.</i> (2016), see text
G. HTM activity duration	hr/day	6.5	Assumed by OEHHA
H. HTM ingestion dose	µg/day	384.6	= D x E x F x G
Total exposure by all pathways			
I. Total daily dose (all pathways)	µg/day	385	= C + H
J. Lifetime averaging factor	unitless	39.2%	= 5 day/7 day x 50 wk/52 wk x 40 yr/70 yr ^a
K. Lifetime average daily dose	µg/day	151	= I x J

^a Section 25721(d)(3) provides a number of assumptions to be used in calculating the reasonably anticipated rate of exposure to carcinogens in the workplace, unless more specific and scientifically appropriate data are available. These include assumptions that workers breathe 10 m³ of air per 8-hour work day, and that the exposure duration for a worker is 50 weeks per year for 40 years.

oehha.ca.gov/media/downloads/cnrn/vinylflooringinstallersud123016.pdf

Residents

154 µg/day

for flooring
containing
20% DINP
by weight

SUD issued
for products
containing
18.9% DINP
by weight,
or less

Table 2. Parameters used in and results of the OEHHA analysis of DINP exposures for residents of homes with vinyl flooring products containing 20% DINP

Parameter	Units	Value	Basis
Inhalation			
A. Airborne gas-phase concentration	µg/m ³	0.207	See Table 3, Line M
B. Particle-air partition coefficient	m ³ /µg	0.023	Weschler and Nazaroff (2010); Liang and Xu (2014)
C. Total suspended particles	µg/m ³	20	Little <i>et al.</i> (2012)
D. Airborne particle-phase concentration	µg/m ³	0.095	= A x B x C
E. Total DINP air concentration	µg/m ³	0.302	= A + D
F. Breathing rate	m ³ /day	19	Age-weighted value calculated based on age-specific values in Section 25721(d)(2)(A)
G. Time spent indoors	unitless	82.4%	US EPA (2011); Table 16-1
H. DINP inhalation dose	µg/day	4.7	= E x F x G
Dermal absorption			
I. Dermal contact surface	m ²	0.44	= 25% of total body surface (age-weighted value calculated based on OEHHA, 2012; Table 6.4)
J. Mass of dust adhered to skin	g/m ² -day	7.1	US EPA (2011, Table 7-23)
K. Human dermal absorption coefficient	unitless	0.15%	McKee <i>et al.</i> (2002); Scott <i>et al.</i> (1987)
L. Skin permeability coefficient	µg/m ² -hr/(µg/m ³)	1.12	Weschler and Nazaroff (2012); Liang and Xu (2014)
M. Dermal intake from dust	µg/day	16	= I x J x K x Q
N. Dermal intake from gas	µg/day	2	= A x G x I x L x 24 h/d
O. Dermal absorption dose	µg/day	18	= M + N
Incidental ingestion			
P. Dust-air partition coefficient	m ³ /µg	0.0165	Liang and Xu (2014); Weschler and Nazaroff (2010)
Q. DINP in dust	µg/g	3415.5	= A x P x 10 ⁶ µg/g
R. Dust ingestion rate	g/day	0.03857	Age-weighted value calculated based on US EPA (2011; Table 5-1)
S. DINP ingestion dose	µg/day	131.7	= Q x R
Total exposure by all pathways			
T. Lifetime daily dose	µg/day	154.5	= H + O + S

oehha.ca.gov/media/downloads/cnrn/sud1supportingmaterials06212016.pdf



SUDs issued for DINP exposures from other products:

- Phifertex® fabric containing up to 25% DINP used in outdoor furniture products
- Single-ply (SP) polyvinyl chloride (PVC) roofing membrane products with a nominal thickness of between 1.016 to 2.438 millimeters (40 to 96 mils), containing no more than 15 percent DINP and heated to surface temperatures up to and including 210°C during installation
- Exposures to residents of homes and other facilities from Tandus Centiva ER3® modular vinyl carpet tiles with a DINP content in the secondary backing layer of 9% by weight, or less, with no DINP present in other parts of the product
- Exposures to professional carpet installers from Tandus Centiva ER3® modular vinyl carpet tiles with a DINP content in the secondary backing layer of 8.7% by weight, or less, with no DINP present in other parts of the product
- Exposures to professional carpet installers and to residents of homes and other facilities from Interface GlasBac® and GlasBac®RE modular carpet tiles where the concentration of DINP in the backing layer is no more than 9% by weight in GlasBac®RE modular carpet tiles and 16.06% by weight in GlasBac® modular carpet tiles; these concentrations are equivalent to a DINP concentration in the whole tile of 5.04% by weight in GlasBac®RE modular carpet tiles and 9% by weight in GlasBac® modular carpet tiles



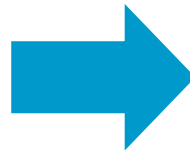
SUDs issued for crystalline silica

- Sorptive mineral-based pet litter
- Interior flat latex paints containing 6% crystalline silica, or less, with diatomaceous earth as the sole source of crystalline silica
 - Assessment took into account exposures that occur when painting and when sanding a painted surface



OEHHA's experience with the SUD process

- Issues related to **communication** can occur throughout the SUD process
- Communications involve multiple parties with variable background/expertise (OEHHA, requestor, technical and legal consultants, testing laboratory)
- **Often must “go through” one party to reach another**
- Communications regarding technical aspects of exposure assessment (e.g., data requirements, modeling), that typically require an understanding of chemicals, products, uses/users, and exposure scenarios **must be accessible to parties with variable background/expertise**



OEHHA's experience with the SUD process

(continued)

- Defining the **scope** of a request (i.e., products and uses/users to be considered) is **key***
- *A scope can be fairly narrow*
 - *One chemical in one type of product (crystalline silica, interior flat latex paint) and its uses (covering interior building walls / ceilings)*
- *A scope can be more broad, covering multiple products or product lines or for multiple uses*
 - *One chemical in multiple (but related) product lines (DINP, vinyl sheet and tile flooring) and uses (covering residential, commercial, office, and other floors)*
- *A scope can take into consideration exposures to different users, such as residential and occupational users*
 - *DINP exposures to professional installers of vinyl flooring and DINP exposures to residents / occupants of buildings with vinyl flooring*

*In reviewing a SUD request for **completeness**, OEHHA looks to see whether the **scope** of a request is supported by the data and information provided



OEHHA's experience with the SUD process

(continued)

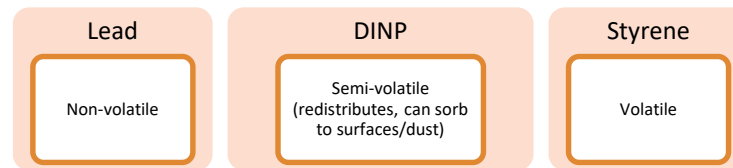
- Obtaining the **data** needed from the business or trade group can be **resource intensive and time consuming**
 - *Existing data (including QA/QC data to allow for evaluation of method/data quality) may not be sufficient for a SUD exposure assessment*
 - Data should be **representative** of the product(s) **within the scope** of the request, covering all relevant exposure routes. For example:
 - FOR PRODUCTS CONTAINING A VOLATILE OR SEMI-VOLATILE PROPOSITION 65-LISTED CHEMICAL, AIR EMISSIONS DATA MAY BE WARRANTED
 - FOR PRODUCTS WITH FOOD CONTACT APPLICATIONS, DATA ON MIGRATION OF THE LISTED CHEMICAL INTO FOOD MAY BE WARRANTED
 - Methods must be scientifically appropriate for chemicals, products, and exposures of concern. For example:
 - IF MIGRATION TESTING IS WARRANTED, IT SHOULD BE PERFORMED UNDER TESTING CONDITIONS (E.G., MIGRATION MATRICES, TEMPERATURE, TIME) APPROPRIATE TO THE PRODUCT'S USE SCENARIO(S)
- *Costs and time considerations associated with data generation may be significant*



OEHHA's experience with the SUD process

(continued)

- **Exposure-related considerations** and **complexity** of exposure assessments (e.g., data and modeling needs) can vary widely across SUD assessments
- *A chemical's properties affect potential exposure routes and pathways and the assessments required to quantify such exposure(s). For example:*



- *Across SUDs for various products (even for the same chemical), differences in use and differences in user populations affect exposure routes and pathways and the assessments required to quantify such exposure(s). For example:*
 - *Inhalation pathway contributes significantly to residents' exposure, but not to exposure to flooring installers' exposure*



SUDs and Alternatives Analysis Thresholds (AATs)

Safe Use Determinations

- Based on exposure assessment: human exposure to a specific chemical(s) from the use of a specific product (or group of products)
 - *SUDs can be specific to a certain type of use or user, e.g., professional installers of vinyl flooring; residents of buildings with vinyl flooring*
- Compares estimated exposure (in $\mu\text{g}/\text{day}$) to a level derived from a dose-response assessment
 - *NSRL: 1 in 100,000 lifetime risk of cancer*
 - *MADL: 1/1,000th of the level at which there are No Observable Effects on reproduction or development*

Alternatives Analysis Thresholds

- Not specified as based on either an exposure or dose-response assessment
 - *Not a safety standard*
- Levels may be set for one or more specific chemicals in a specific Priority Product
 - *For contaminants, the AAT is equivalent to the Practical Quantitation Limit, unless DTSC sets an alternative, higher level*



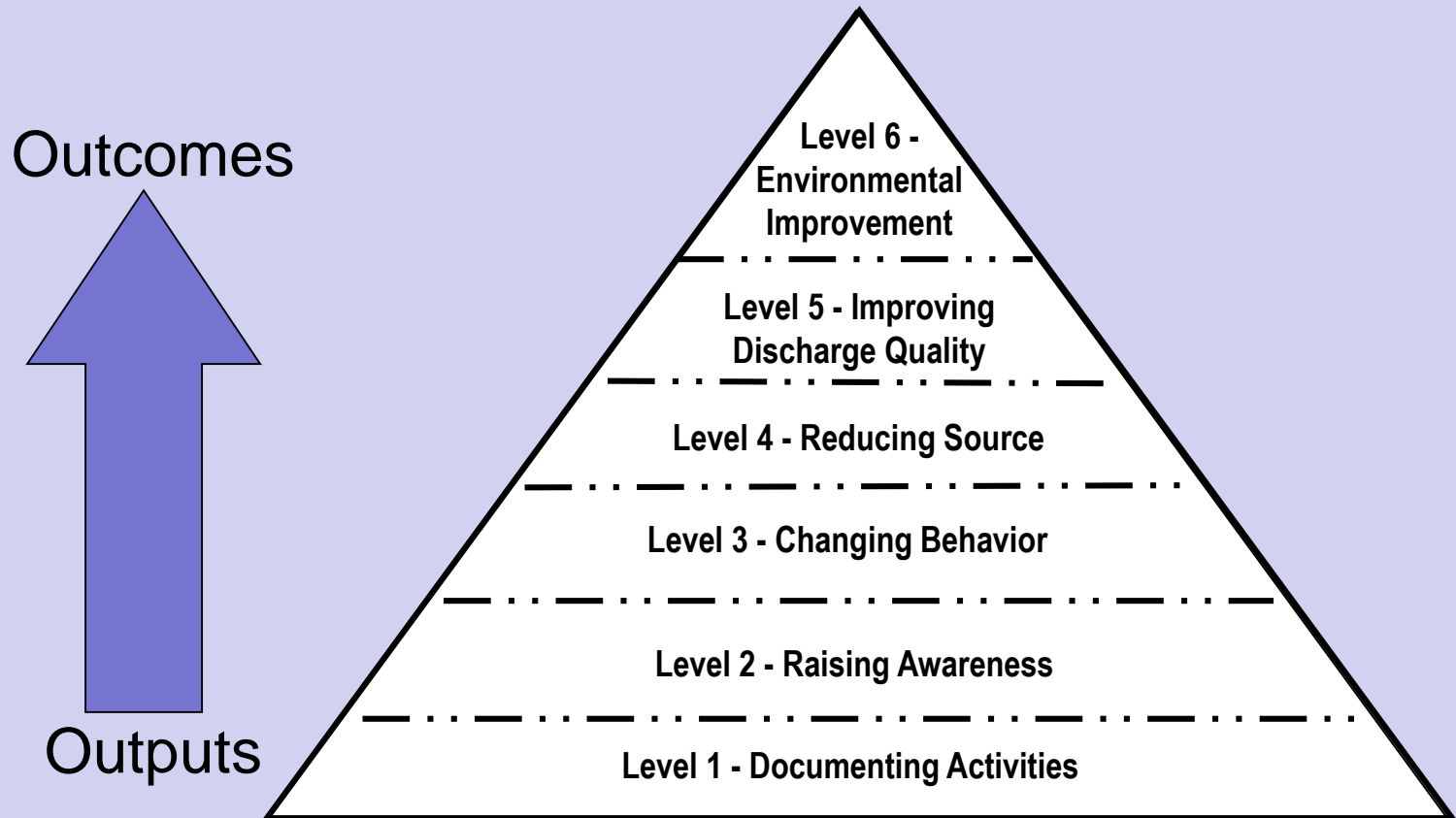
Questions for AAT Discussion

- What should SCP take in to consideration when setting an AAT?
- How do we ensure protection against hazardous chemicals in the face of practical constraints (e.g. feasibility)?
- What are the consequences of setting an AAT from a technical perspective and for stakeholder's perception of the program? How do we ensure that an AAT is not confused with a safety assessment such as a SUD?
- Should SCP set AATs at all given the potential implications that there is an acceptable level of a hazardous chemical and implies a risk assessment calculation and mindset? If not, how would you recommend that we determine the PQL?



Water Quality Program Evaluation Metrics

Adapted from California Stormwater Quality Association *Municipal Stormwater Program Effectiveness Assessment Guidance* (2007)





Safer Consumer Products Program Metrics

Green Ribbon Science Panel April 23, 2019

Karl Palmer, Acting Deputy Director
Safer Products and Workplaces Program



Department of Toxic Substances Control



CalEPA

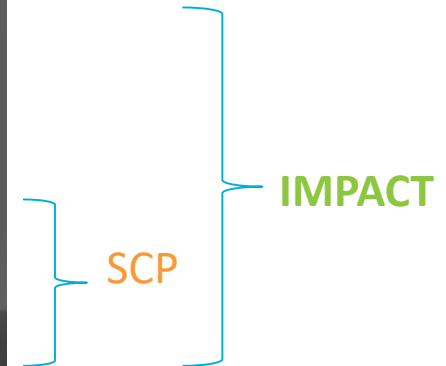
Why metrics?

- Performance assessment – are we achieving mission?
- Process improvement
- “AA” – what works?
- Prioritization



History

- Not new territory, nor new challenges;
 - How do you measure prevention?
 - How do you attribute or allocate specific contributions to successful outcomes?
 - Are there indicators?
- P2
- EPIC
- Biomonitoring



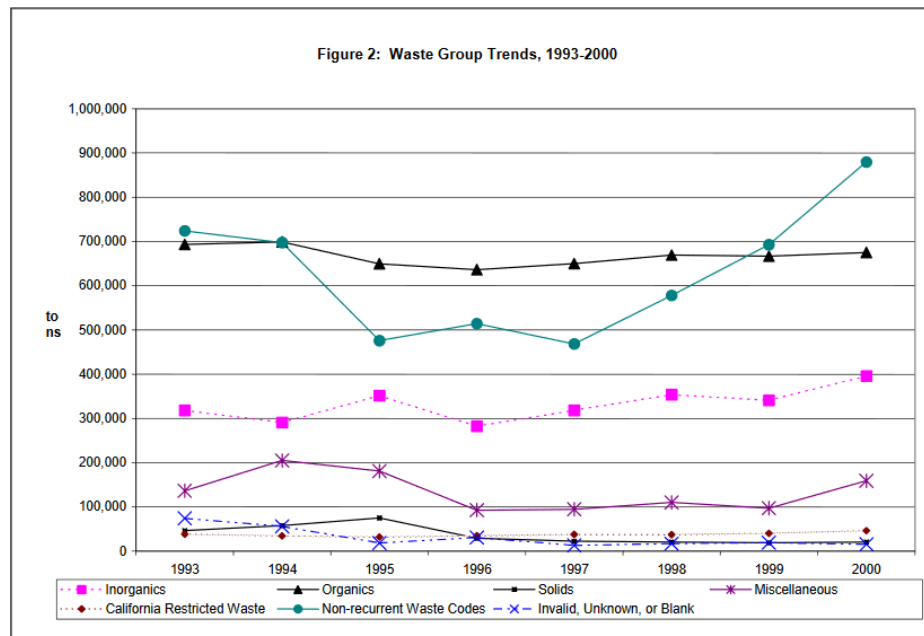
$$(\text{SCP})xyz^2 + \text{GRSP} + \text{Ef} = \text{IMPACT}$$



P2

Sector-based approach:

- Evaluation of waste stream data in HW Tracking System
- ID sectors of interest, based on volume of HW and potential P2 opportunities



P2: Education – Training – Implementation?

Training Workshop Survey Results


- 680 people attended training session: 52% responded to surveys distributed;
- familiarity with P2 workshop topics: 23% of responders were not familiar with the topics; 53% were somewhat familiar;
- DTSC received positive responses to the questions on whether operators would consider implementing one or more VSR Best Management Practices (BMP). For example:
- aqueous parts cleaning: 27% said they were currently using aqueous parts cleaning and 42% said they would consider converting to aqueous parts cleaning in the future;
- aqueous brake cleaning: 45% of responders were using aerosol brake cleaners; 38% would consider using aqueous brake washing system;
- reusable oil filters: 3% are currently using, 27% said they would consider using them; and
- oil-life extension: 9% are currently analyzing oil and extending time between oil changes, 26% would consider using this method.



P2 Example

■ Development of Green Business Program Database

VSF Metric



Use an aqueous parts washer instead of a solvent tank.


- Savings: VOC emissions, lbs hazardous waste reduced
- Inputs: # solvent tanks replaced

Calculation

VOC emissions reduced = $0.6 \text{ lbs/day} * 365 * \text{\# of solvent tanks replaced}$

lbs of hazardous waste reduced = $600 \text{ lbs/year/unit replaced}$

Assumptions/Conversions:
0.6 lb/day VOC per unit was established by BAAQMD Staff report, on regulation 8, Rule 16, 2002 found here: http://www.baaqmd.gov/pln/ruledev/8-16/2002/0816_sr_sept2002.pdf
Assumes 30 gallon solvent tank changed 4 times per year, compared to 30 gallon aqueous unit changed once per year = $600 \text{ lbs/year/unit replaced}$



ENVIRONMENTAL INNOVATIONS

50

Slide courtesy of Environmental Innovations



EPIC – Environmental Protection Indicators for California

- Identified 84 indicators from broad array of air quality, water quality/supply, waste management, human health and ecosystem health

INDICATOR STATUS	
I. Adequate data collected to assess trends	<ul style="list-style-type: none"> Number of days with unhealthy ozone, carbon monoxide, and/or particulate matter (PM₁₀) Number of coastal beaches posted or closed Per capita amount of solid waste generation, diversion, and disposal Number of hazardous materials spills and releases Total reported occupational illnesses and injuries associated with pesticide exposure Status of threatened and endangered species Extent of change in range land and forest habitat Air temperature
II. Further data collection or analysis needed to assess trends	<ul style="list-style-type: none"> Total emissions of toxic air contaminants (TACs) Magnitude of groundwater contaminant plumes Extent of cleanup of illegal solid waste disposal sites Volume of hazardous waste imported or exported Number of growers adopting reduced-risk pest management systems Status of the northern spotted owl
III. No ongoing data collection	<ul style="list-style-type: none"> Extent of indoor exposure to formaldehyde Number of environmental releases from active landfills Levels of mercury in human blood and other tissues Quantity of endocrine-disrupting chemicals in aquatic ecosystems



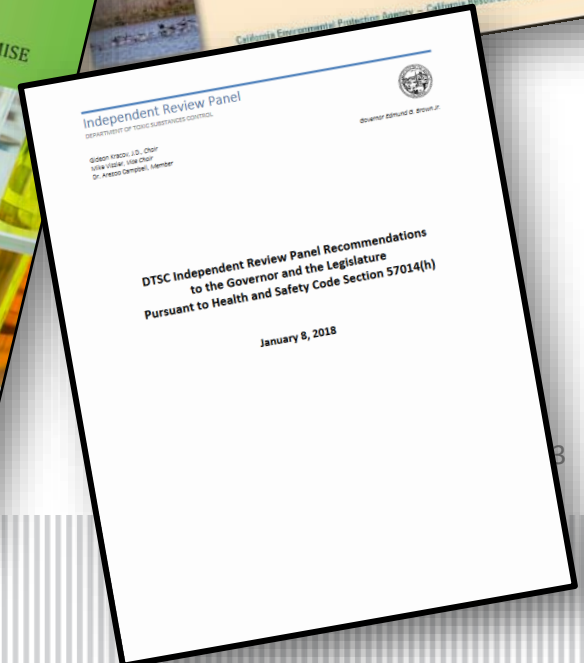
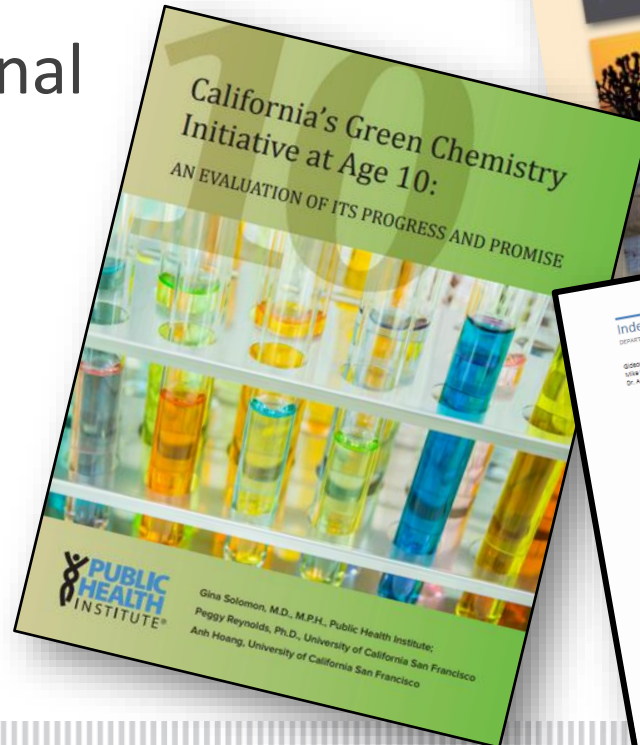
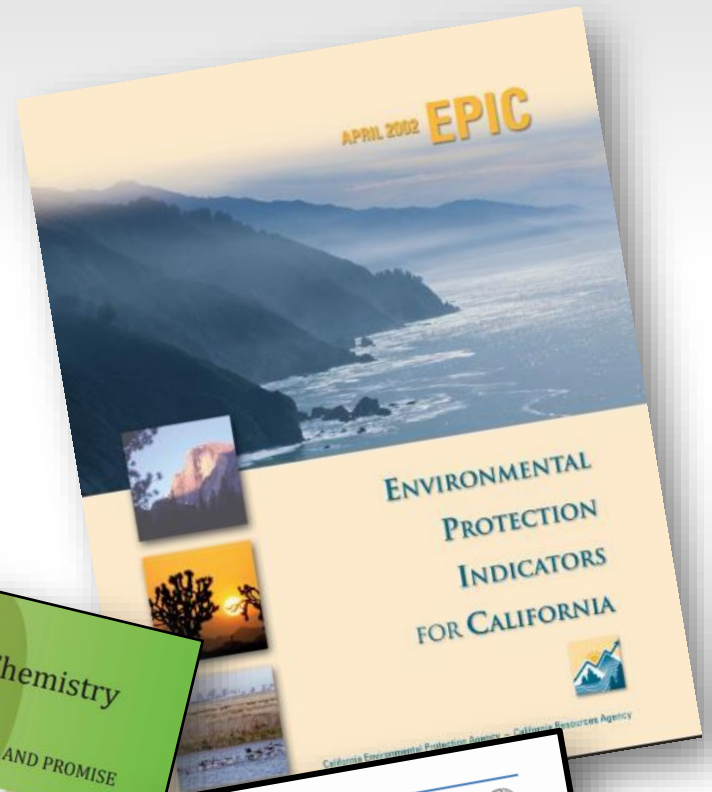
Biomonitoring

- California Regional Exposure (CARE) Study - Study of metals and other environmental chemicals in adults across the state, conducted one region at a time
- Population/Chemical specific studies, e.g.:
 - Firefighter Occupational Exposures (FOX) Project
 - Foam Replacement Environmental Exposure Study (FREES)
- Future studies?



Focus and Value

- Short term vs. long term
- Outputs vs. Outcomes
- Perceptions vs. Observations
- Internal vs. External



Key steps...

- Ask the right questions
- Learn from others
- Identify tools and methodologies
- Planning and Investment
- Tracking and monitoring





Studying regulatory impact

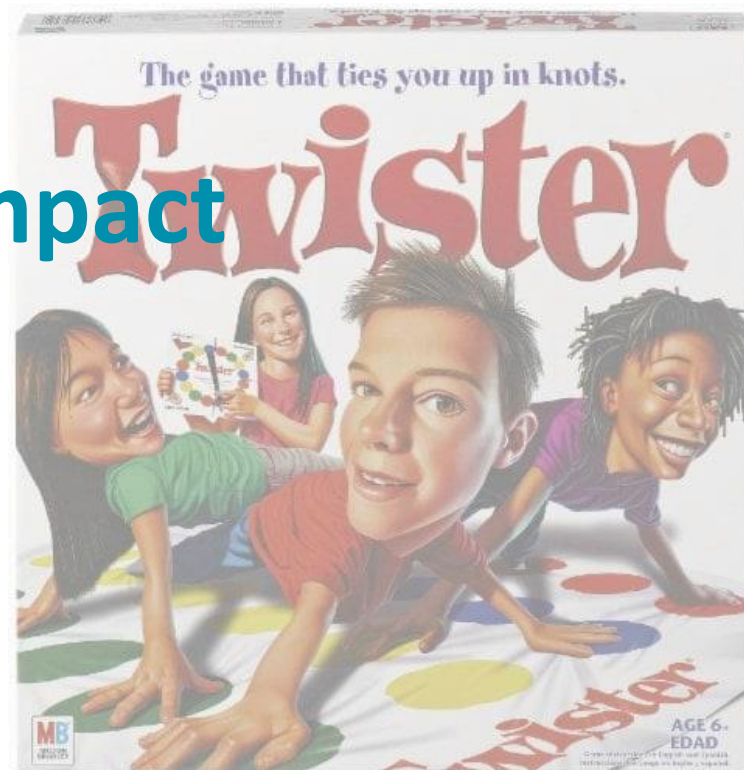
It's really hard after-the-fact



Green Ribbon Science Panel Meeting

April 23, 2019

Meg Schwarzman, MD, MPH



Department of Toxic Substances Control



CalEPA

Impact of Prop 65 on Chemical Exposures Relevant to Breast Cancer

CBCRP Award ID: 23QB-1881 ♦ 2017-2020

Goal: Determine whether and how Proposition 65 has affected population-level exposures to chemicals linked to breast cancer.

Aim 1 - Investigate *population-level shifts in exposures to Prop 65 chemicals* (mammary carcinogens, mammary gland developmental toxicants, EDCs)

Aim 2 - Investigate *changes in consumer and worker perceptions* and behaviors as a result of Proposition 65 warnings and public education campaigns

Aim 3 - Assess *changes in business practices* associated with chemical listing under Proposition 65

Aim 4 - Assess *mechanisms* of Prop 65 impact and *trends in enforcement* actions

- *Identify particularly effective elements of the law*
- *Identify potential enhancements*



Impact of Prop 65 on Chemical Exposures Relevant to Breast Cancer

CBCRP Award ID: 23QB-1881 ♦ 2017-2020

Research Team



UC Berkeley:

- Meg Schwarzman, MD, MPH - PI
- Claudia Polsky, JD – Legal analysis
- Purba Mukerjee, JD – Legal Fellow
- Samantha Schildroth – Grad student researcher



Silent Spring Institute:

- Ruthann Rudel, MS – Senior Scientist
- Robin Dodson, PhD – Data analysis
- Jennifer Ohayon, PhD – Post doc researcher

Advocate partners:

- Breast Cancer Prevention Partners
- Bluegreen Alliance
- CHAMACOS
- Black Women for Wellness



**BLUEGREEN
ALLIANCE**



Proposition 65: Three key mechanisms

1. Creates a hazard-based list of chemicals and mixtures

- ✓ Carcinogens, Reproductive and Developmental toxicants

2. Prohibits discharges

- ✓ ...of Prop 65 chemicals to drinking water sources

3. Requires risk-based warnings

- ✓ Requires “clear and reasonable warnings” before exposing consumers, workers, communities to a Prop 65 chemical in product...
- ✓ ...at a level associated with a significant risk
- ✓ Enforcement by public (Attorney General) and private citizens (NGOs, law firms)
- ✓ Burden on defendant to prove exposure to the Prop 65 chemical poses no significant risk



Project aims to determine impact of Prop 65 by:

1. Investigating *population-level shifts in exposures* to Proposition 65 chemicals
 - Analyze **biomonitoring** data for changing levels of targeted chemicals before/after listing or enforcement
 - Analyze **consumer product ingredient** data
 - Analyze **environmental data** for changes in emissions
2. Assessing *changes in business practices* due to chemical *listing* and *enforcement* actions
 - Evaluate evidence of **reformulation**: consumer product data, business interviews,
 - Evaluate evidence of **changing chemical use** (sources as above)
 - Assess any observed changes in light of enforcement actions (public and private)
3. Evaluating *indirect impacts* of P65 on:
 - State and municipal regulation
 - Standards and 3rd party certifications
 - Hazard screening tools
 - Advocacy lists and actions
 - Retailers, product manufacturers, and brands
4. Understanding consumer and worker perceptions and behaviors
 - Focus groups
 - Analysis of Federal HazCom standard as means of P65 workplace enforcement
5. Understanding *mechanisms* of Prop 65 impact and assess *trends in enforcement* actions
 - Identify particularly effective elements of the law
 - Identify potential enhancements



1. Population-level shifts in exposures to Prop 65 chemicals

a. Analyze **biomonitoring** data for changing levels of targeted chemicals before/after listing or enforcement

- *NHANES, including a data-center proposal for CA-specific data*
- *Biomonitoring CA data – earliest data 2006 so limited to a few recently added Prop 65 chemicals; studies not comparable*
- *Limited data on multiple members of same chemical class*
- *Confounded by many other forces affecting chemical use*
- *The problem of California vs. the nation*

b. Analyze **consumer product ingredient** data for changes in chemical use in specific product categories

- *CARB consumer product survey data for VOCs and SVOCs*
- *Patchwork quilt of data collection since 1997*
- *Limited to information at level of product categories*

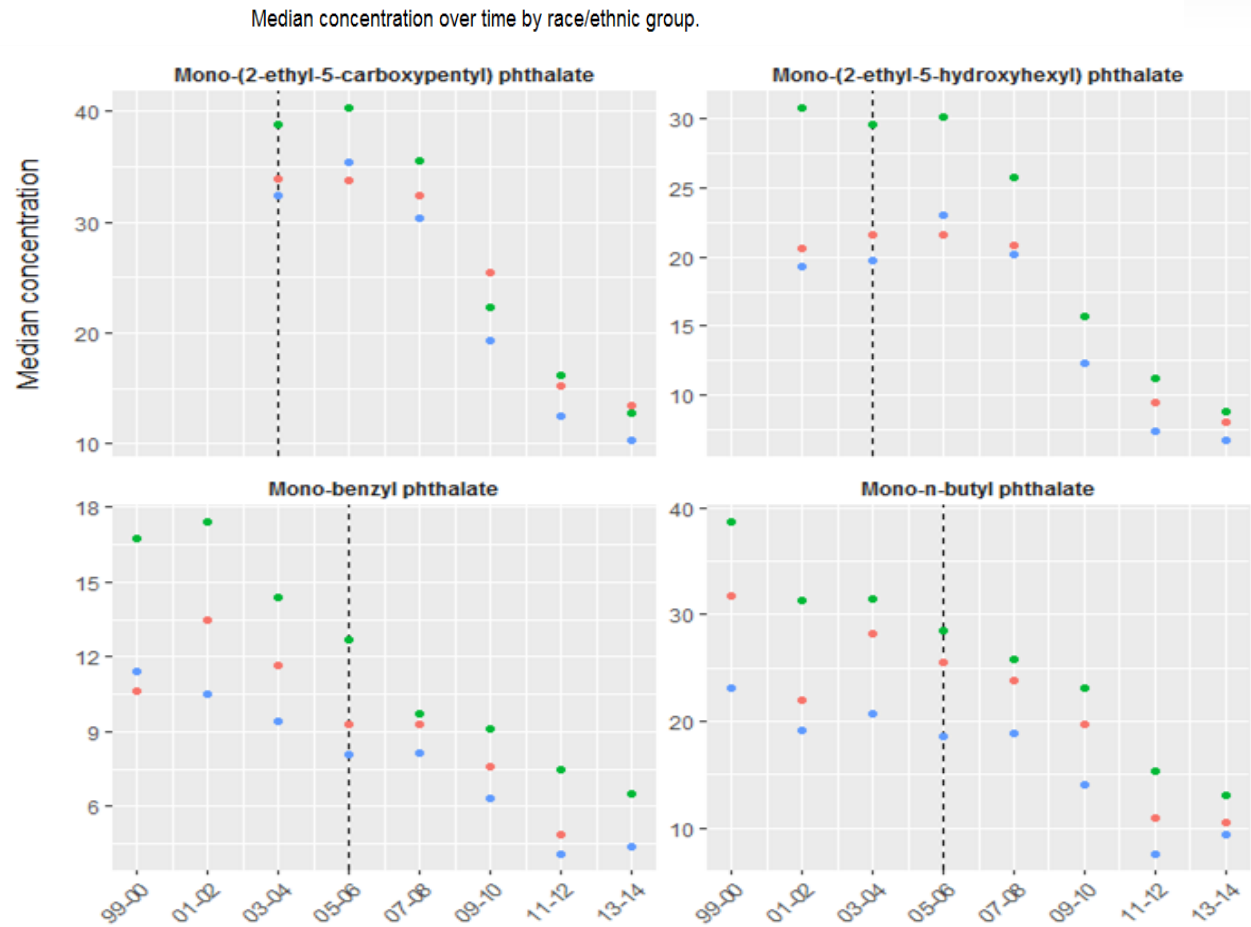
c. Analyze **environmental data** for changes in emissions and discharges

- *HotSpots data on air emissions from stationary facilities*
- *TRI emissions for national level – reporting changes*
- *No luck yet on sources of data on discharges to water*



1.a. Biomonitoring findings from NHANES for select phthalate metabolites relative to P65 listing date

PRELIMINARY DATA
DO NOT CITE



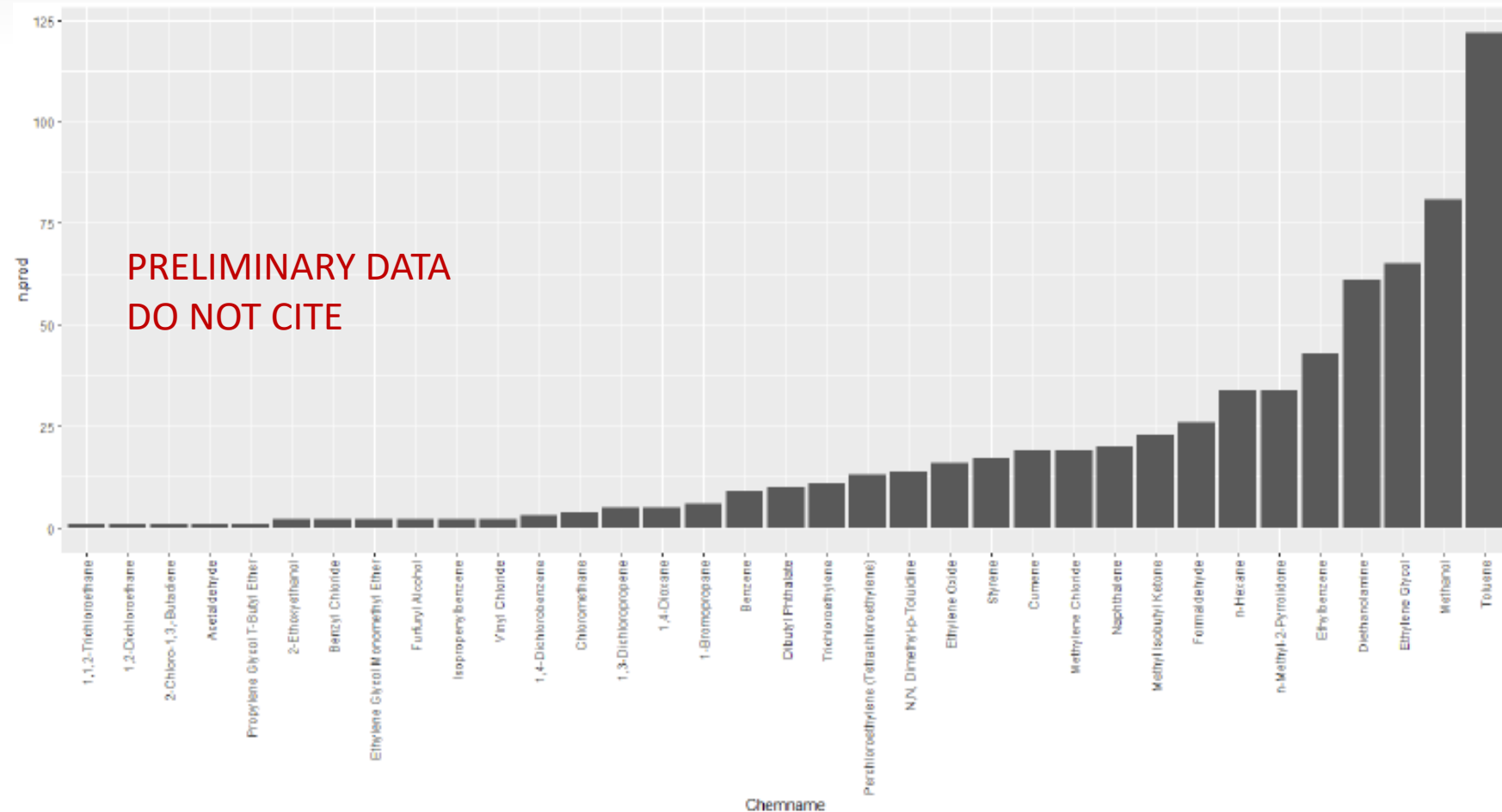
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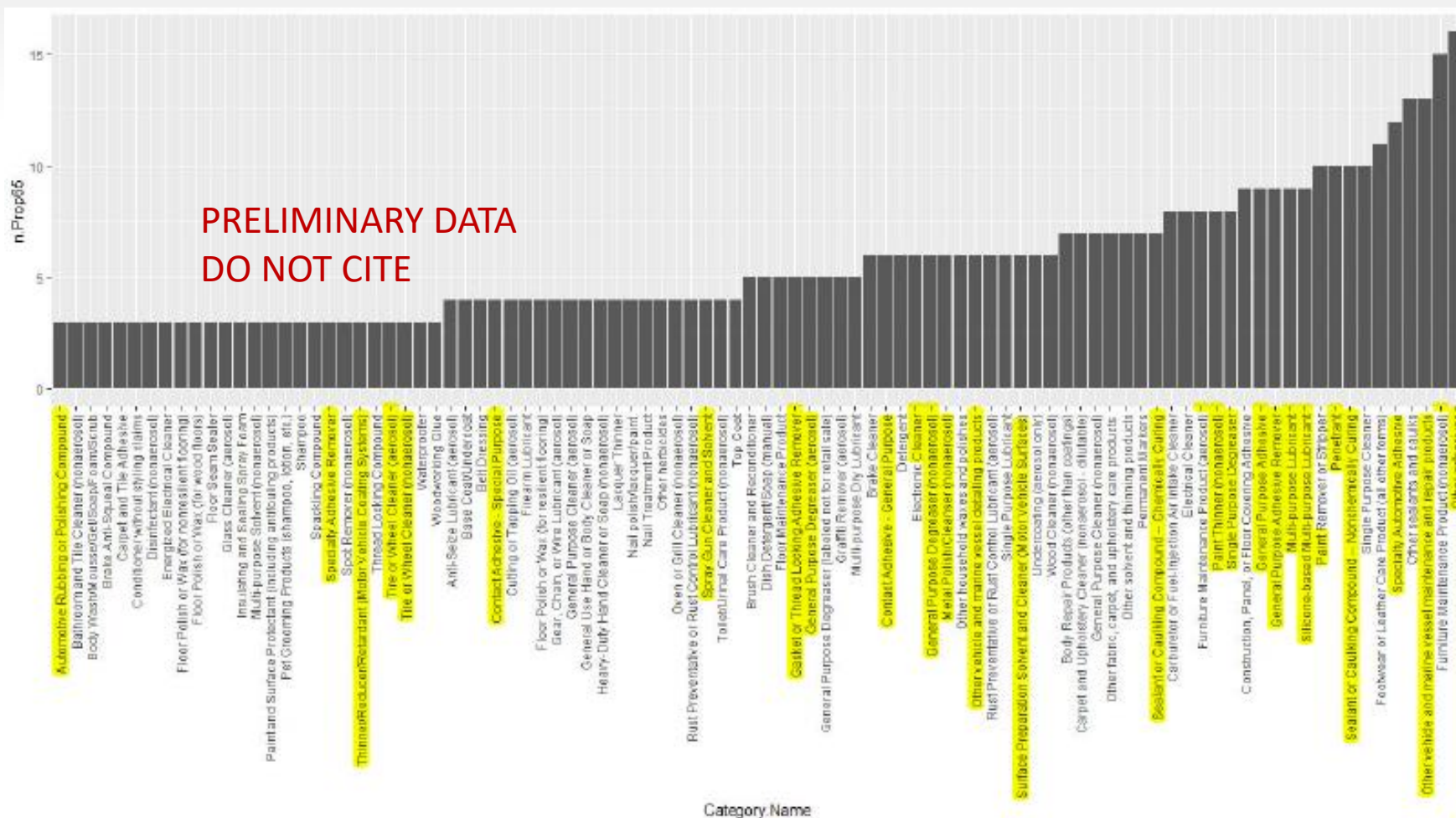


1.b. Data from CARB Consumer Product Surveys

Prop 65 chemicals most frequently reported, by product category



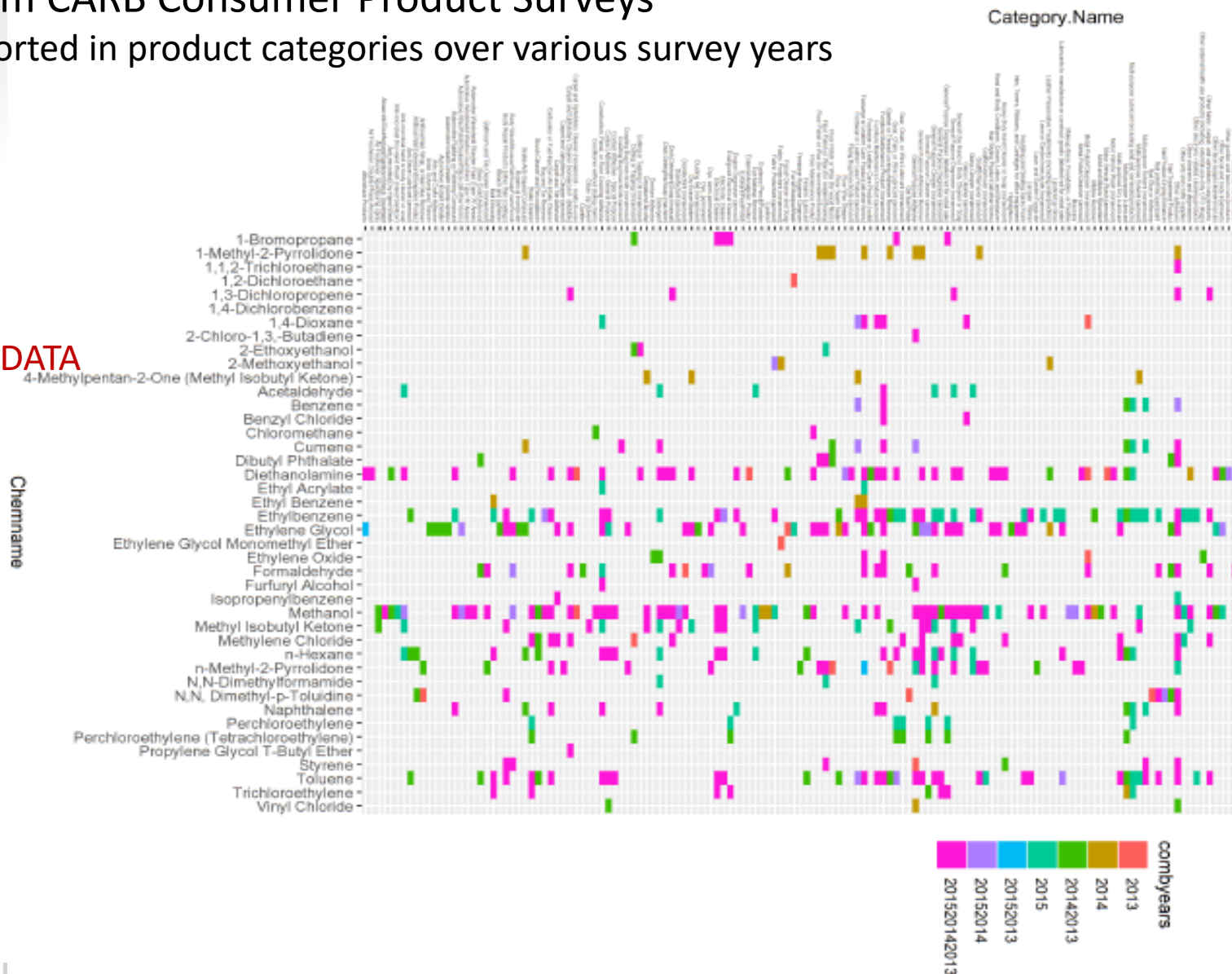
Product categories containing highest number of Prop 65 chemicals



1.b. Data from CARB Consumer Product Surveys

Chemicals reported in product categories over various survey years

PRELIMINARY DATA
DO NOT CITE



1. Population-level shifts in exposures to Prop 65 chemicals

- a. Analyze **biomonitoring** data for changing levels of targeted chemicals before/after listing or enforcement
 - *NHANES, including a data-center proposal for CA-specific data*
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 - *Limited to information at level of product categories*
- c. Analyze **environmental data** for changes in emissions and discharges
 - *HotSpots data on air emissions from stationary facilities, confounded*
 - *TRI emissions for national level – reporting changes, confounded*
 - *No luck yet on sources of data on discharges to water*



2. Changes in business practices due to listing and enforcement

a. Evaluate evidence of **reformulation**

- Business interviews
- Consumer product data (as in 1.)
- Targeted product testing

b. Evaluate evidence of **changing chemical use** for specific product categories

- Biomonitoring data
 - Environmental monitoring data
 - Ingredient information (consumer product data)

a. Assess any observed changes in light of enforcement actions (public and private)

- Use of AG database of private enforcement
- Interviews with AG office staff about public enforcement actions (e.g., Port of LA and diesel exhaust)



3. Indirect (non enforcement-related) impacts

a. State and municipal regulation

- *E.g., SB 258 Cleaning products ingredient disclosure requires ingredient labels for all intentionally added P65 chemicals by 2023;*
- *CA Air Toxics Information and Assessment Act (1987) a.k.a Hot Spots. Requires stationary sources emissions reporting for P65 chemicals (and 5 other lists).*
- *Maine cites P65 as source of reproductive toxicants*

b. Standards and 3rd party certifications

- *E.g., Green Seal 14 standards (out of 33) covering 1,200 products prohibit P65 reproductive toxicants. Used by major purchasers (municipalities, universities, etc.)*

c. Hazard screening tools

- *E.g., Green Screen List Translator – P65 chemicals are Bench Mark 1*

d. Retailers, product manufacturers, and brands

- *E.g., Restricted substance lists (RSLs), retailer chemical policies*

e. Advocacy lists and actions

- *E.g., Prop 65 list recapitulated by Mind the store, campaign for Safe Cosmetics, etc.*



For the SCP program: how not to get tied up in knots

1. Build in the mechanisms for data collection NOW, avoid Twister later
 - What are key objectives? What changes are you hoping to see?
2. Track product reformulations
 - Passively – via CARB data
 - Actively – via product testing
 - Proactively – via mandated reporting (SB 392?)
3. Targeted environmental monitoring is easier than biomonitoring
 - E.g., Indoor dust for SVOCs
4. Partner with OEHHA/CDPH on targeted biomonitoring studies
 - Consider evaluating products in work plan (not only PP)
 - Include multiple chemicals in class that are likely substitutes (e.g., phthalates)
 - Propose topic to CBCRP?
 - SCP provides another reason to expand the CARE study
5. Identify and track indirect impacts
 - E.g., who is using the candidate chemical list and how? Who is responding to the work plan and how?



For SCP program: how not to get tied up in knots

6. Identify areas where SCP may contribute in a unique way and assess those
 - E.g., Prop 65 as authoritative list of reproductive toxicants
 - For SCP: chemical class listings, key product categories, industrial uses of methylene chloride
7. Inquiries can quickly become data-process intensive
8. Anecdotal and descriptive information is valuable too!
 - Informative in its specificity– what caused change in this case?
 - Has a storytelling value
9. Observe changes in product composition, not “decreased” level of chemical of concern
10. Don't be paralyzed by the issue of confounding
 - Problem or opportunity? California vs. the nation
 - Look for unique contributions (e.g., methylene chloride)
 - Compare outcomes for targeted vs. non-targeted chemicals
 - Check back with me in 1.5 years!



Questions for SCP Metrics Discussion

- Which metrics are most applicable, achievable, and informative for SCP?
- What metrics are used in similar programs (WA Dept of Ecology, EPA's Safer Choice, Massachusetts TURI)?
- Which metrics are currently available and obtainable; which ones are promising, but need further research to be useable?
- Are there agencies, organizations, or researchers we should collaborate with to obtain the necessary metric data?
- What challenges do you envision for SCP as we work to establish metrics?
- How can we best convey success to the public and legislators?



Metrics: U.S. EPA SCP's Use of Metrics to Gauge Progress and Milestone Achievements

Presented at the DTSC Green Ribbon SCIENCE Panel Meeting

April 23, 2019

Margaret H. Whittaker

ToxServices LLC



Learn About the Safer Choice Label

EN ESPAÑOL

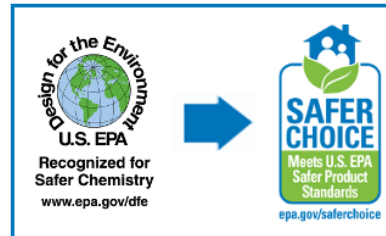
About Safer Choice

What does the Label Mean?

Safer Choice Information

Same program, new label

Finding cleaning and other products that are safer for you, your family, and the environment should be easy — that's why we developed our new Safer Choice label. We all play a role in protecting our families' health and the environment. Products with the Safer Choice label help consumers and commercial buyers identify products with safer chemical ingredients, without sacrificing quality or performance.



More than 2,000 products currently qualify to carry the Safer Choice label. Safer Choice products are available [for your home at retail stores](#) and [for use in facilities like schools, hotels, offices, and sports venues](#).

For the past 15 years EPA's label for safer chemical products has been known as the Design for the Environment, or the "DfE," label. We spent more than a year collecting ideas and discussing new label options with stakeholders, such as product manufacturers and environmental and health advocates. Then we took our ideas to consumers and asked what worked best for them. The result is the new Safer Choice label.



Department of Toxic Substances Control



CalEPA



Where can I find Safer Choice-certified products?

For a complete list of Safer Choice-certified products visit our [product webpage](#). As of January 2015, about 2,250 products qualify to carry the label and new products are always being added. You will start to find Safer Choice-certified products at most stores that carry cleaning and household supplies, including major nationwide retailers and thousands of independent stores, as early as the spring and summer of 2015.



Department of Toxic Substances Control



CalEPA



Department of Toxic Substances Control



CalEPA

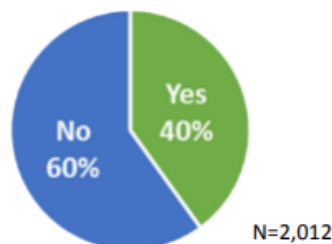
Survey of Consumer Awareness



In a survey of 2,000+ adult U.S. residents in February 2016:

- 40% of consumers reported familiarity with the program.

Are you familiar with a labeling program implemented by EPA that enables consumers to select products...safer for people, families, and pets?



- 35% of consumers say they have seen the Safer Choice label on store shelves.



Department of Toxic Substances Control

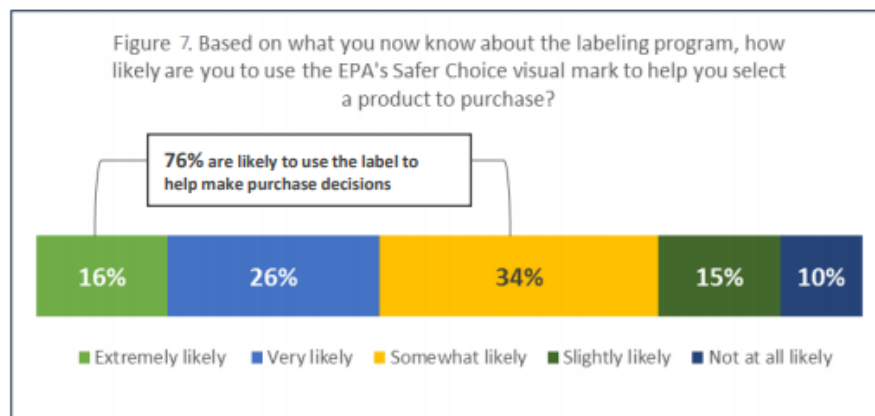


CalEPA

Consumer Desire to use Safer Choice



- **76%** of consumers... responded that they would use the Safer Choice label to inform purchasing decisions.
 - **83%** of parents...
 - **86%** of millennials...



Department of Toxic Substances Control



CalEPA

Success of the New Label



- *Consumer Reports (May 2015):*
“Why We Like the Label”
- *Recent Survey by a Leading Retailer:*
 - Majority of shoppers would purchase a product to try it solely because it carries the Safer Choice label
- Increasing presence in federal purchasing



Department of Toxic Substances Control



CalEPA

Safer Chemical Ingredients List



Safer Chemical Ingredients List

- The listed chemicals are safer alternatives, grouped by their [functional-use class](#).[†]
- Chemicals are marked as a [green circle](#), [green half-circle](#), [yellow triangle](#), or [grey square](#).[‡]
- This list includes many of the chemicals evaluated through the Safer Choice Program. It does not include confidential chemicals. There may be chemicals not included in this list that are also safer.
- Some of the listed chemicals may not be on the [TSCA inventory](#) and therefore may not be authorized/allowed for TSCA uses. Those considering TSCA uses for these chemicals should first determine whether such use is authorized. Chemicals not listed on the TSCA inventory are indicated as such in a pop-up box that appears upon clicking the hyperlinked CAS RN in the table below.

♦ Please Select: [All Functional Use Classes](#)

♦ or Select a Functional Use Class:

- [Antimicrobial Actives](#)
- [Chelating Agents](#)
- [Colorants](#)
- [Defoamers](#)
- [Emollients](#)
- [Enzymes and Enzyme Stabilizers](#)
- [Fragrances](#)
- [Oxidants and Oxidant Stabilizers](#)
- [Polymers](#)
- [Preservatives and Antioxidants](#)
- [Processing Aids and Additives](#)
- [Skin Conditioning Agents](#)
- [Solvents](#)

New
Look!

Chelating Agents

Note: When a functional use category is selected, the search above will only apply to the chemicals assigned to this functional use. To select a different functional use, please [scroll up](#).

Show 25 entries

Code	Common Name	CAS Registry Number	Functional Use
	2-Hydroxyethane-1,1-dicarboxylic acid (EDTA), ammonium salt (1:1), homopolymer, hydrolyzed, sodium salt	182828-08-8	Chelating Agents
	Alamine, N,N-bis(carboxymethyl)-, sodium salt (1:1)	164962-16-2	Chelating Agents

New
Search Bar!

- [Specialized Industrial Chemicals](#)
- [Surfactants](#)
- [Uncategorized](#)

♦ Search: Name or CAS RN

From 450 to 824
chemicals in four years



Department of Toxic Substances Control



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Additions to SCIL



- 100 new chemicals, including:
 - 35 new Surfactants
 - 13 new Solvents
 - 9 new Processing Aids & Additives
- 2 new categories
 - Emollients
 - Skin Conditioning Agents



Department of Toxic Substances Control



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Market-ready ingredients



- GreenBlue's CleanGredients is one source of such information
- GreenBlue outreach to suppliers
- It is easier and more cost-effective to list new ingredients
- 495 ingredients listed currently
 - 92 new ingredients
 - 33 new ingredients added to functional classes that previously had none
- 57 active suppliers
 - 14 new suppliers listing their ingredients



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Challenges and Opportunities Posed by Mixtures Assessment in SCP-Related AAs

Presented at the DTSC Green Ribbon SCIENCE Panel Meeting

April 23, 2019

Margaret H. Whittaker
ToxServices LLC



Department of Toxic Substances Control



CalEPA

Overview: To Discuss

- Status Quo: What are the primary barriers to assessing chemistry and toxicity of mixtures?
- What existing mixtures-related tools, frameworks/models, and ongoing efforts should be considered for the SCP Program?
- What Can AA Community learn from the risk assessment community when assessing mixtures?
- What are existing mixtures-related frameworks and how applicable are these frameworks to SCP Program?
- Resources



Mixtures Assessment...Is Complicated!

- **Mixtures** – The consideration of mixtures toxicity is a “hot potato” in the risk assessment and AA communities!
- Answering AA-related questions requires an understand of mixtures chemistry and toxicity during both stages of SCP's AA process:
 - Is this ingredient necessary?
 - Is there a safer alternative?
 - Have regrettable substitutes been avoided?

The screenshot shows the Chemical Watch website. A yellow circle highlights the headline "Mixtures assessment may require complete rethink, says JRC". Below the headline, the text reads: "Key report outlines major challenges with risk assessment and management". The date "4 April 2019 / Europe, Mixtures" is shown. The article text states: "It may be time for a 'complete rethink' of how risks posed by chemical mixtures are assessed and managed, according to the European Commission's Joint Research Centre. Developing risk management measures for chemical mixtures is a 'major challenge', according to the JRC, which has carried out a review. The overall risk may come from:". Below the text is a small image of a laboratory flask. To the right of the article, there are three promotional banners: "TSCA Coverage highlights", "The new Chemical Watch has arrived...", and "ENVIRO Helping you stay one step". At the bottom of the article, it says "Taylor & Francis" and "OPEN ACCESS".

Chemical Watch

Search Chemical Watch...

Home News TSCA Brexit TSCA Reports Guides/databases Events Jobs

Mixtures assessment may require complete rethink, says JRC

Key report outlines major challenges with risk assessment and management

4 April 2019 / Europe, Mixtures

It may be time for a "complete rethink" of how risks posed by chemical mixtures are assessed and managed, according to the European Commission's Joint Research Centre.

Developing risk management measures for chemical mixtures is a "major challenge", according to the JRC, which has carried out a review. The overall risk may come from:

» chen

CRITICAL REVIEWS IN TOXICOLOGY
<https://doi.org/10.1080/10408444.2019.1579169>

REVIEW ARTICLE

Regulatory assessment and risk management of chemical mixtures: challenges and ways forward

Stephanie K. Bopp, Aude Kienzler, Andrea-Nicole Richarz, Sander C. van der Linden, Alicia Pains, Nikolaos Parisis and Andrew P. Worth

European Commission, Joint Research Centre (JRC), Ispra, Italy

Taylor & Francis
Taylor & Francis Group

OPEN ACCESS Check for updates

TSCA Coverage highlights

The new Chemical Watch has arrived...

ENVIRO Helping you stay one step

<https://www.tandfonline.com/doi/pdf/10.1080/10408444.2019.1579169?needAccess=true>
&



ASPHALT EXAMPLE FORMULATIONS

Example #1 – Hot Mix Non-Modified

Table 1: Example #1 - Hot Mix Asphalt (Non-Modified)

Chemical Name	CAS#	% Composition
Limestone	1317-65-3	50-100%
Carbonic acid, magnesium salt (1:1)	546-93-0	≤ 50%
Quartz	14808-60-7	0.1 - 15%
Asphalt	8052-42-4	0.1 - 10%

Table 2: Example #2 – Hot Mix Asphalt (Modified)

Chemical Name	CAS#	% Composition
Petroleum Asphalt	8052-42-4	57-75%
Water	7732-18-5	55-75%
Naphtha	64741-46-4	0-10%
Polymer Additive	9003-55-8	0-5%
Emulsifier	61790-37-2	0- 6%
Hydrochloric Acid	7647-01-0	0-6%
Hydrogen Sulfide	7783-06-4	Trace

Example #3 – Rubberized Asphalt

Table 3: Example #3 - Rubberized Asphalt

Chemical Name	CAS#	% Composition
Petroleum Asphalt	8052-42-4	40-95%
Vacuum Distillate	64741-53-3	0-20%
Petroleum Distillate	64741-96-4	0-20%
Hydro treated Heavy Naphthenic Distillate	64742-52-5	0-20%
Styrene-Butadiene Block Copolymer	9003-55-8	0-15%
Ethylene-Butadiene Block Copolymer	66070-58-4	0-15%
Vulcanized Rubber Compound	120-78-5	0-25%
Mineral Filler	1317-65-3	0-50%
Polyester Fibers	25038-59-9	0-10%

These three formulations are each asphalt products:

--Very different formulations

--Just testing one “mixture” of asphalt will not characterize hazards of all “asphalt formulations”



Challenges with Assessing Mixtures

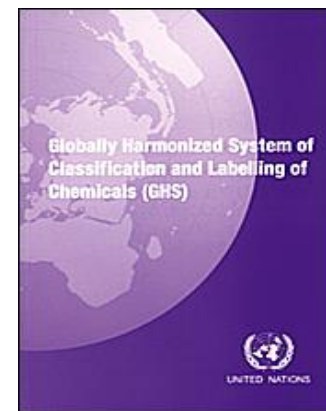
- The most straightforward approach to assess the toxicity of a mixture is to simply test the mixture in order to directly estimate its potential for harm
- **BUT**
 - In vivo toxicity testing of mixtures is expensive, does not account for countless permutations in a mixture, and raises ethical issues because it harms or kills animals
 - Mixtures testing will not identify specific chemicals responsible for the response (important factor for product optimization)
 - As a result, New Approach Methodologies (NAMs) feature prominently in characterizing hazards of mixtures, while GHS can be used to classify hazards of mixtures



Tools for Mixtures Screening: GHS to the Rescue

Quick Refresher!

- GHS classifies three types of hazards: health, physical, and environmental hazards
- There are three main components of GHS:
 - Hazard classification, Chemical labelling, and Safety Data Sheets
- For hazard classification, GHS assigns hazard class and hazard category
 - **GHS hazard class** represents the nature of a chemical hazard, e.g., flammable liquids, carcinogen
 - **GHS hazard category** is numerical classification within each hazard class. e.g., Acute toxicity has 5 hazard categories, with Cat 1 being worst



GHS: Seventh edition (2017)






Tools for Screening Mixtures: GHS

- GHS describes the nature and severity of hazard class and hazard category
 - There are 29 hazard classes (left columns below)
 - Hazard class and category are summarized in H statements
 - **H2xx: Physical hazards**
 - **H3xx: Health hazards**
 - **H4xx: Environmental hazards**



**Free on-line tool to look up
all 107 H statements:**
[http://www.chemsafetypro.com/
Topics/GHS/GHS_hazard_statem
ent_code_signal_word_finder.ht
ml](http://www.chemsafetypro.com/Topics/GHS/GHS_hazard_statement_code_signal_word_finder.html)

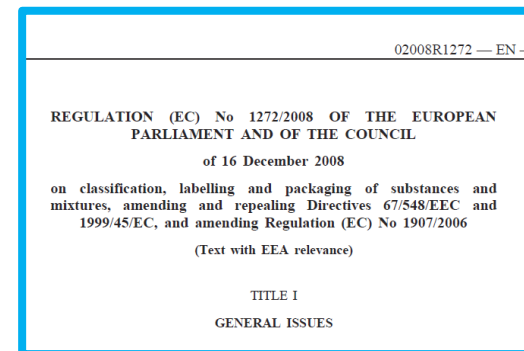
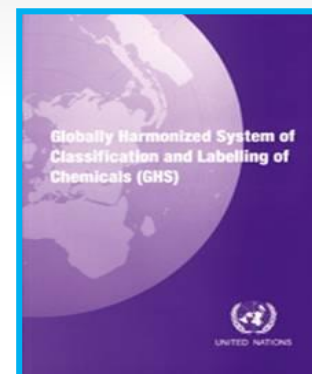
GHS Hazard Classifications by Endpoint	
GHS Health Hazards	High Hazard  Low Hazard
Acute Toxicity	Categories 1, 2, 3, 4, 5
Skin Corrosion/Irritation	Categories 1 (1A, 1B, 1C), 2, 3
Serious Eye Damage/Eye Irritation	Categories 1, 2 (2A, 2B)
Respiratory or Skin Sensitization	Category 1 (1A, 1B)
Germ Cell Mutagenicity	Categories 1 (1A, 1B), 2
Carcinogenicity	Categories 1 (1A, 1B), 2
Reproductive Toxicity	Categories 1 (1A, 1B), 2
Specific Target Organ Toxicity Single Exposure	Categories 1, 2, 3
Specific Target Organ Toxicity Repeated Exposure	Categories 1, 2
Aspiration Hazard	Categories 1, 2

GHS Physical Hazards	High Hazard  Low Hazard
Explosives	Divisions 1.1, 1.2, 1.3, 1.4, 1.5, 1.6
Flammable gases & chemically unstable gases	Categories 1, 2 & A, B
Aerosols	Categories 1, 2, 3
Oxidizing gases	Category 1
Gases under pressure	Compressed/Liquefied/Refrigerated liquefied/ Dissolved Gas
Flammable liquids	Categories 1, 2, 3, 4
Flammable solids	Categories 1, 2
Self-reactive substances and mixtures	Types A, B, C and D, E and F, G
Pyrophoric liquids/solids	Category 1
Self-heating substances and mixtures	Categories 1, 2
Substances and mixtures which, in contact with water, emit flammable gases	Categories 1, 2, 3
Oxidizing liquids/solids	Categories 1, 2, 3
Organic peroxides	Types A, B, C, D, E, F, G
Corrosive to metals	Category 1
GHS Environmental Hazards	High Hazard  Low Hazard
Acute aquatic hazard	Acute categories 1, 2, 3
Chronic aquatic hazard	Chronic categories 1, 2, (3), 4

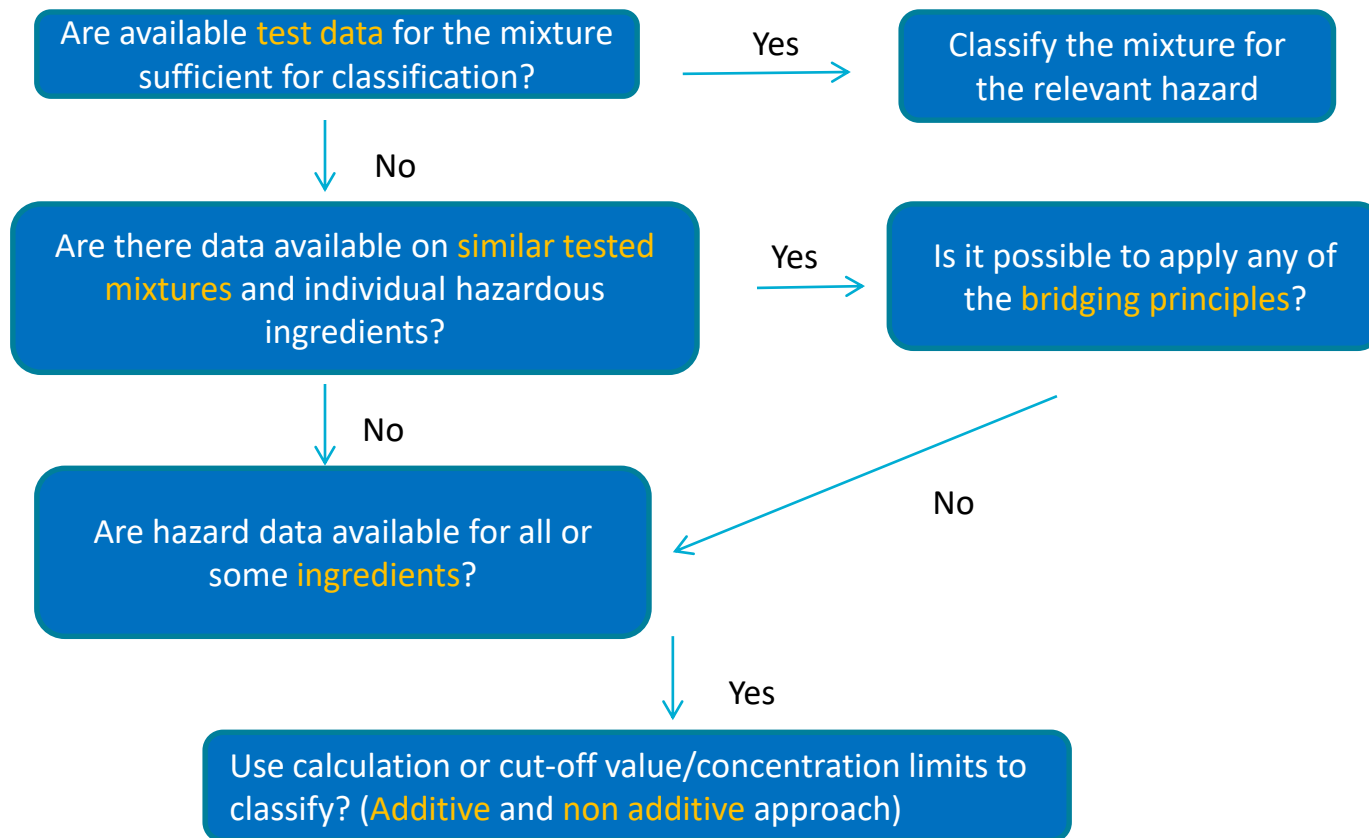


Mixtures Toxicity Within GHS

- GHS provides guidance on hazard classification of chemical mixtures for physical, human health, and the aquatic environment
 - Physical hazards classification based on testing
 - Health and environmental hazards based on individual ingredients
- Countries have adopted GHS into their legal frameworks:
 - EU adopted as part of REACH (CLP)
 - USA adopted in 2012 (OSHA HazCom)
- Idea: SCP PAA and AA templates could include a section for the Responsible Entity to use GHS to classify hazards of the original formulation and proposed alternative formulation using GHS Mixtures Rules



GHS Tiered Approach to Mixture Classification



GHS Classification of a Mixture Based on its Components

NON-ADDITIVE APPROACH

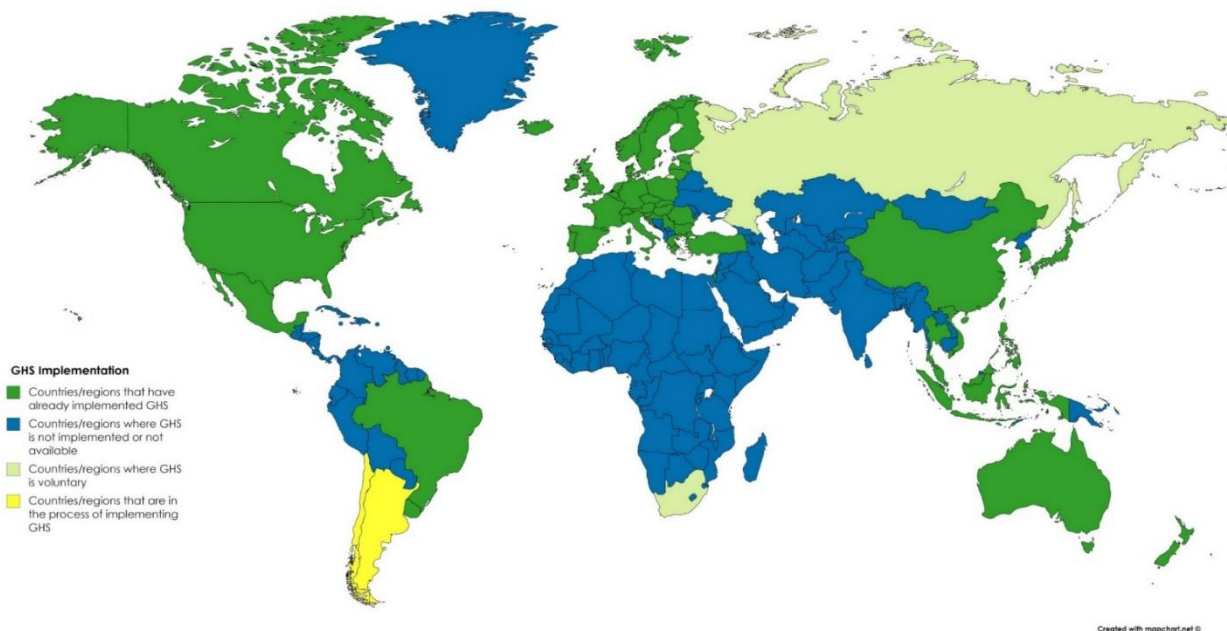
- Mixture contains at least one chemical present at or above the GCLs defined for that hazard class; the mixture will be classified for that hazard.
- Applied for the following hazard endpoints:
 - Carcinogenicity, Mutagenicity and Reproductive Toxicity
 - Systemic Toxicity/Organ Effects (ST)(Single Exposure)
 - Systemic Toxicity/Organ Effects (ST)(Repeated Exposure)
 - Skin and respiratory sensitizers

ADDITIVE APPROACH

- The concentrations of the ingredients with the same hazard are added together and if the sum equals or exceeds the GCL set out for this hazard class/category, the mixture must be classified for that hazard.
- Applied for following hazard endpoints:
 - Skin Irritation
 - Eye Irritation
 - Acute Aquatic Toxicity
 - Chronic Aquatic Toxicity



Tools for Mixtures Screening: Caveat Emptor w/ SDS!



GHS is implemented in only 72 countries (green shading)

GHS is **not** implemented in many countries (blue shading)

- Most of Africa
- India (still in process of implementing)
- Bangladesh

Warning! Disclosure on SDS is incomplete, so use these “tools” carefully!
Case in point: environmental hazards do not have to be disclosed on OSHA-Compliant SDS!



Tools for Mixtures Screening: Caveat Emptor w/ SDS!

■ What is on a Safety Data Sheet?

- The SDS is a 16-section document that discloses hazards, provides information about proper transportation, disposal, exposure controls, and chemical composition
- Sections 11 through 15 of an SDS are required under GHS, but they are not mandatory under the revised OSHA Hazard Communication Standard:

- *Toxicological Information*
- *Ecological Information*
- *Disposal Considerations*
- *Transport Information*
- *Regulatory Information*


} Voluntary sections of an OSHA HCS-compliant SDS

Do not assume a mixture has been correctly classified on an SDS!

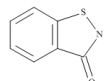


Reminder: Not All Hazards are Disclosed on SDS

HEALTH HAZARD

- Glyoxal (CAS #107-22-2) 
 - Crosslinker; Used as an intermediate in wrinkle-resistant textile formulations
- Mutagenic (among other hazards)
 - H341: Suspected of causing genetic defects
 - GHS Category 2

ENVIRONMENTAL HAZARD (NOT LEGALLY REQUIRED ON U.S. SDS!!)

- 1,2-Benzisothiazol-3(2H)-one (CAS #2634-33-5) 
 - Preservative
- Aquatically toxic (acute)(among other hazards)
 - H400: Very toxic to aquatic life
 - GHS Category 1 acute aquatic toxicity

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2, H315

Eye irritation, Category 2, H319

Skin sensitisation, Category 1, H317

Germ cell mutagenicity, Category 2, H341

For the full text of the H-Statements mentioned in this Section, see Section 16.

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 4), H302

Skin irritation (Category 2), H315

Serious eye damage (Category 1), H318

Skin sensitisation (Category 1), H317

Acute aquatic toxicity (Category 1), H400

For the full text of the H-Statements mentioned in this Section, see Section 16.



Unnamed Lubricant

- Section 2 of the SDS discloses many hazards with this lubricant

- Side-note:

- *H statements on U.S. SDS do not include their corresponding H statement numbers (not a legal requirement in the U.S.)*



Hazard Statements

Keep out of reach of children.
Read label and SDS before use.
May be fatal if swallowed and enters airways.
May cause drowsiness or dizziness.
Causes skin and serious eye irritation.
Combustible liquid

LUBRICANTS

Safety Data Sheet
Prolink Chain Lube

SECTION 1: Identification

Trade Name: Prolink Chain Lube
ID Number: 6698
Synonyms: Solvent blend
Product Use Description: Lubricant
Manufactured By: PROGOLD LUBRICANTS
PO BOX 80729
Conyers, GA 30013 US
Date Prepared: 01/31/2017
Website: www.progoldmfr.com
24 HR Emergency Number: (800) 535-0000

SECTION 2: Hazards Identification

Classifications
Flammable liquids - Category 4
Aspiration Hazard - Category 1
Eye Irritation - Category 2
Skin Irritation - Category 2
Specific Target Organ Toxicity (single exposure) - Category 3



Unnamed Lubricant SDS, cont'd

SECTION 12: Ecological Information

Not available.



Does no disclosure in Section 12 mean no hazards?!

Short Answer: **No!! (because this section is voluntary in US HCS-compliant SDS)**



New Approach Methodologies (NAMs): NAMs to the Rescue!



- GHS mixtures rules can classify hazards of mixtures, but this assumes that each relevant hazard for mixture's subcomponents has data sufficient to classify the hazard
- However, data for an entire slew of health, environmental, and physical endpoints is generally lacking! This is where NAMs enter the scene.
- What are New Approach Methodologies (NAMs)?
- NAM comprises *in vitro*, *ex vivo*, or 'omic technologies, as well as *in silico* and toxicokinetic modeling approaches

[Home](#)

Communiqué Blog

Read-Across Uncertainties in Risk Assessments: NAM to the Rescue!

For those of us in the risk assessment arena, deriving health reference values with a classic animal-based approach is part skill and part habit, honed by years of scouring *in vivo* studies to identify critical health effect endpoints, executing dosimetric conversions to deduce human equivalent doses, and, more recently, grouping chemicals based on structural or mechanistic similarities to support read-across. The presenters during the 2018 Annual Meeting and ToXExpo Workshop Session "Reducing the Uncertainty of Read-Across Predictions by New Approach Methodologies: Application in Regulatory Human Risk Assessments" gave us good reason to abandon old habits and embrace new approach methodologies (NAM).

The acronym "NAM" is pronounced alternatively like dram (as in a wee dram of spirits) or nom (as in a mystery word my son used to describe food groups when he was younger). NAM comprises *in vitro*, *ex vivo*, or 'omic technologies, as well as *in silico* and toxicokinetic modeling approaches.

Work is underway in the United States and EU to develop NAM-based approaches to facilitate animal-free hazard and risk assessment, as evidenced by the EU-ToxRisk Programme's 30 million euro investment in NAM approaches. Although the European

Recent Stories

IUTOX 15th International Congress of Toxicology (ICTXV): Book Housing Now
Updated 8:51AM EDT, Mon Apr 22nd, 2019

Exclusive room rates for the IUTOX 15th International Congress of Toxicology (ICTXV), co-hosted by SOT, are available until June 14 and June 26. Attendees should plan to book their stay as soon as pos...








SOT FDA Colloquium Series Continues May 15 with Focus on In Silico Methods
Updated 4:31PM EDT, Thu Apr 18th, 2019

SOT and the US Food and Drug Administration (US FDA) Center for Food Safety and Applied Nutrition (CFSAN) will hold a


CRITICAL REVIEWS IN TOXICOLOGY
<https://doi.org/10.1080/10408444.2019.1579169>



REVIEW ARTICLE

Regulatory assessment and risk management of chemical mixtures: challenges and ways forward

Stephanie K. Bopp , Aude Kienzler , Andrea-Nicole Richarz , Sander C. van der Linden , Alicia Paini , Nikolaos Parisis  and Andrew P. Worth 

European Commission, Joint Research Centre (JRC), Ispra, Italy


 Taylor & Francis
Taylor & Francis Group

 OPEN ACCESS
  Check for updates



New Approach Methodologies (NAMs): NAMs to the Rescue!



Review

Exploration of Computational Approaches to Predict the Toxicity of Chemical Mixtures

Supratik Kar and Jerzy Leszczynski *

Interdisciplinary Center for Nanotoxicity, Department of Chemistry, Physics and Atmospheric Sciences,
Jackson State University, Jackson, MS 39217, USA; supratik.kar@icnanotox.org

* Correspondence: jerzy@icnanotox.org; Tel.: +1-601-979-3723; Fax: +1-601-979-7823

Received: 22 January 2019; Accepted: 14 March 2019; Published: 19 March 2019



<https://www.mdpi.com/2305-6304/7/1/15/pdf>

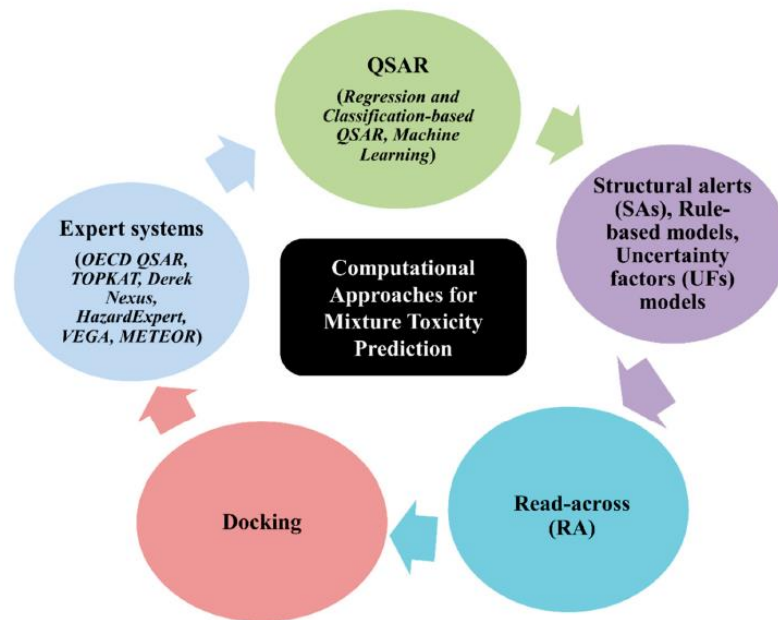
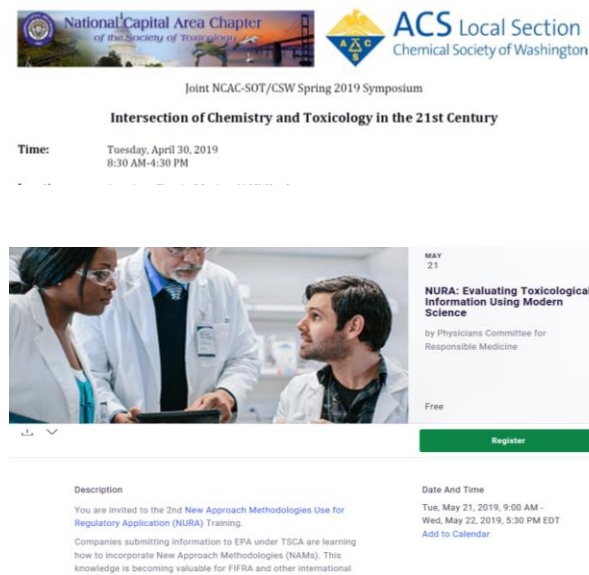


Figure 3. Types of computational approaches for the prediction of toxicity.



Resources Related to Mixtures

- Identifying “safer” mixtures is part detective work **and** part science!
 - Start first by identifying chemicals used in formulations....then...
 - Use NAMs to fill hazard datagaps, then Use GHS Mixtures Rules to classify the overall hazard of the mixture
- Where to get training in NAMs, GHS, Datagap Filling?
 - **SOT Symposium: Intersection of Chemistry and Toxicology in the 21st Century, April 30, 2019 in Washington, D.C.**
 - *In-Person and Video Webcast:*
<http://www.toxicology.org/groups/rc/ncac/events.asp>
 - **PCRM’s Two Day Workshop NAMs for Use in Regulatory Application (NURA) training, May 21-22, 2019 in Gaithersburg, Md. Workshop is Free!**
 - *In-Person and Video Webcast:* <https://www.pcrm.org/ethical-science/animal-testing-and-alternatives/nura/modern-science>
 - **UL is holding a two-day GHS course in Pittsburgh on June 11-12, 2019**
 - https://psi.ul.com/en/training/ghs-essentials/?utm_source=GeniusMonkey_VT



National Capital Area Chapter
of the Society of Toxicology

ACS Local Section
Chemical Society of Washington

Joint NCAC-SOT/CSW Spring 2019 Symposium

Intersection of Chemistry and Toxicology in the 21st Century

Time: Tuesday, April 30, 2019
8:30 AM-4:30 PM

NURA: Evaluating Toxicological Information Using Modern Science
by Physicians Committee for Responsible Medicine

Free

Register

Description
You are invited to the 2nd New Approach Methodologies Use for Regulatory Application (NURA) Training. Companies submitting information to EPA under TSCA are learning how to incorporate New Approach Methodologies (NAMs). This knowledge is becoming valuable for FIFRA and other international

Date And Time
Tue, May 21, 2019, 9:00 AM -
Wed, May 22, 2019, 5:30 PM EDT
[Add to Calendar](#)



THANK YOU

mwhittaker@toxservices.com – 202-429-8787



Questions for Chemical Mixtures Evaluation Discussion

- How is a chemical mixture practically defined in your work?
- To what extent should the SCP program consider the effects of chemical mixtures in prioritizing Priority Products and evaluating chemical substitutions? What are the benefits and challenges or knowledge gaps in considering chemical mixtures?
- What approaches to evaluate mixtures would the Panel recommend DTSC consider? Do these approaches differ when considering ecological impacts?
- What existing tools, models, and ongoing efforts for mixture evaluation would the Panel consider particularly useful for SCP?



Questions for Chemical Mixtures Evaluation Discussion

- What regulatory frameworks exist for chemical mixture regulation and how applicable are these frameworks to the California SCP program?





Green Ribbon Science Panel Meeting

April 23 - 24, 2019 – Sacramento, California

Meeting Materials can be found at:

https://dtsc.ca.gov/SCP/GRSP/April_23-24_2019.cfm



Department of Toxic Substances Control



CalEPA



Public Comments

Submit your comments to

SaferConsumerProducts@dtsc.ca.gov



Department of Toxic Substances Control



CalEPA



SCP Alternatives Analysis Review

Green Ribbon Science Panel Meeting April 24th, 2019

Xiaoying Zhou, Ph.D., P.E., Senior Hazardous Substances Engineer,
Safer Products and Workplaces Program



Department of Toxic Substances Control



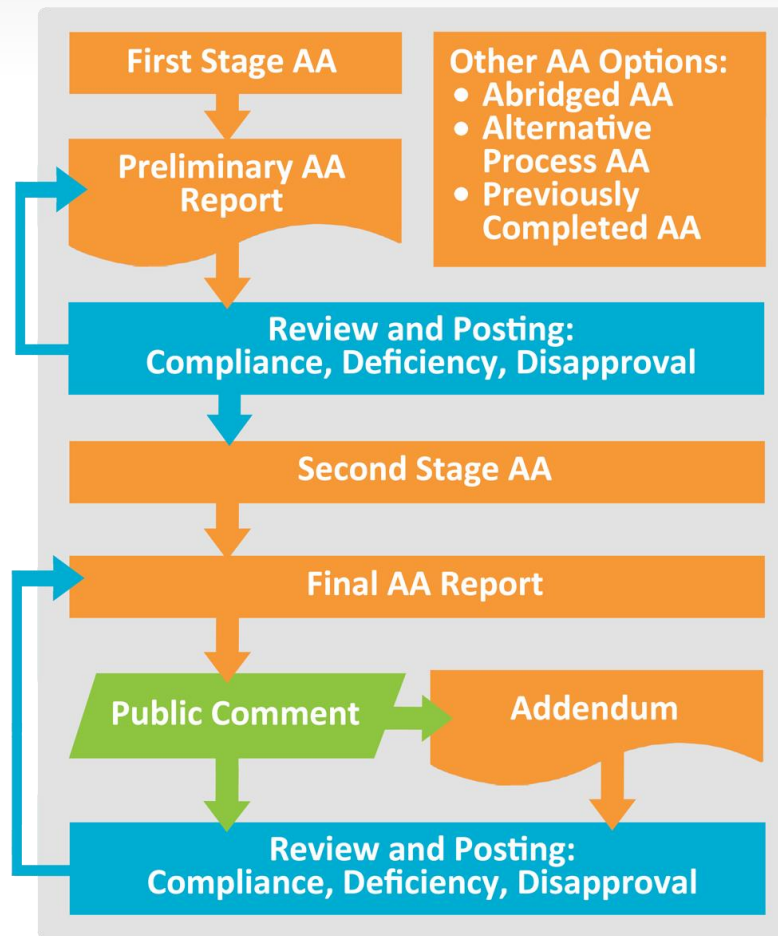
CalEPA

Outline

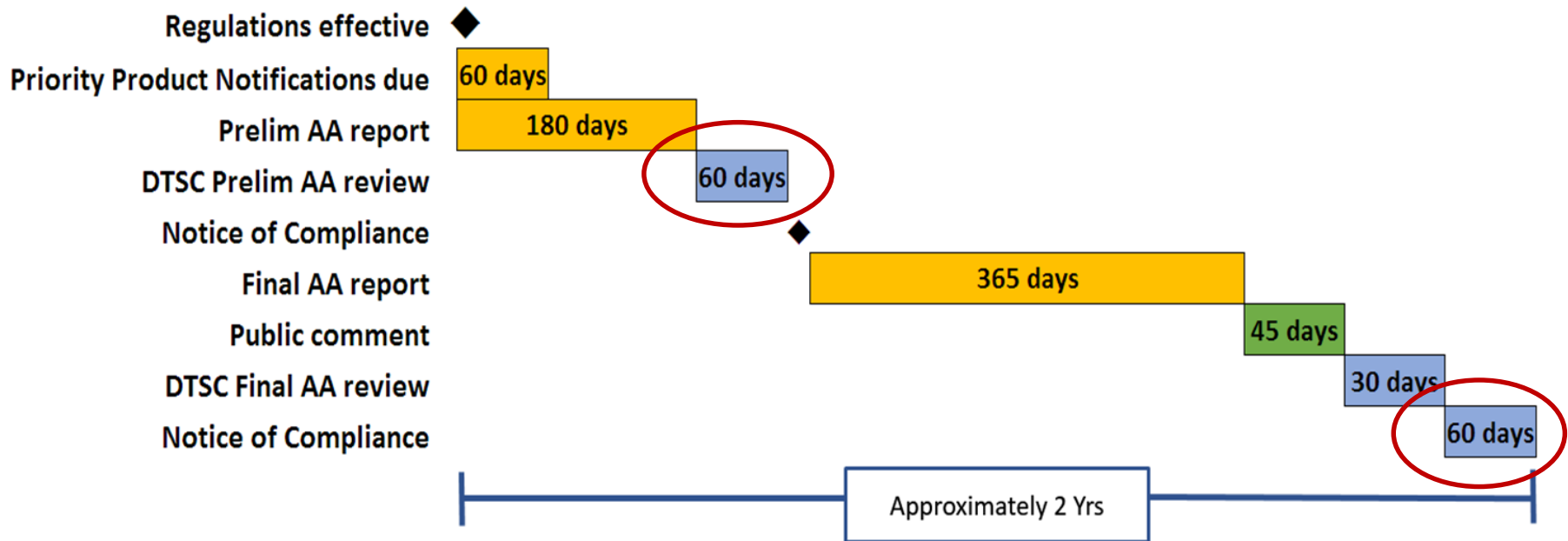
- Introduction
- Challenges anticipated
- SCP AA review process and preparation
- Questions to GRSP panel



Recap of SCP Alternatives Analysis Process



Approximate Timeline



Approximate workload for AA review in 2019

- Paint or Varnish Strippers with Methylene Chloride
 - *Effective Jan 1, 2019; Priority Product Notifications (PPNs) due Mar 4; Preliminary AA Reports Due Jul 1, 2019.*
 - *10 manufacturers have submitted 10 PPNs (10 REs, 49 products) and one manufacturer has submitted one product removal confirmation.*
 - ***9 REs, 48 products** to follow up: Removal/replacement notifications, Preliminary AA, Abridged AA.*
 - *Some AAs may be conducted by consortium*
- Spray Polyurethane Foam (SPF) Systems with Unreacted Methylene Diphenyl Diisocyanates (MDI)
 - *PPNs due Apr 26; Preliminary AA Reports Due Aug 26, 2019.*
 - *3 manufacturers have submitted 3 PPNs (**3 REs, 33 products**).*



AA Reports and Review Criteria

- General requirements and contents (CCR Section 69505.7)

- Review Criteria (CCR Section 69505.8(a))

➤ *Whether the AA Report*

➤ *Whether, and to what extent, the AA Report complies with the applicable provisions of an AA Report;*

➤ *Whether, and to what extent, the AA Report complies with the applicable provisions of the AA Report.*

See Supporting Document #3

Reliable information

(A)

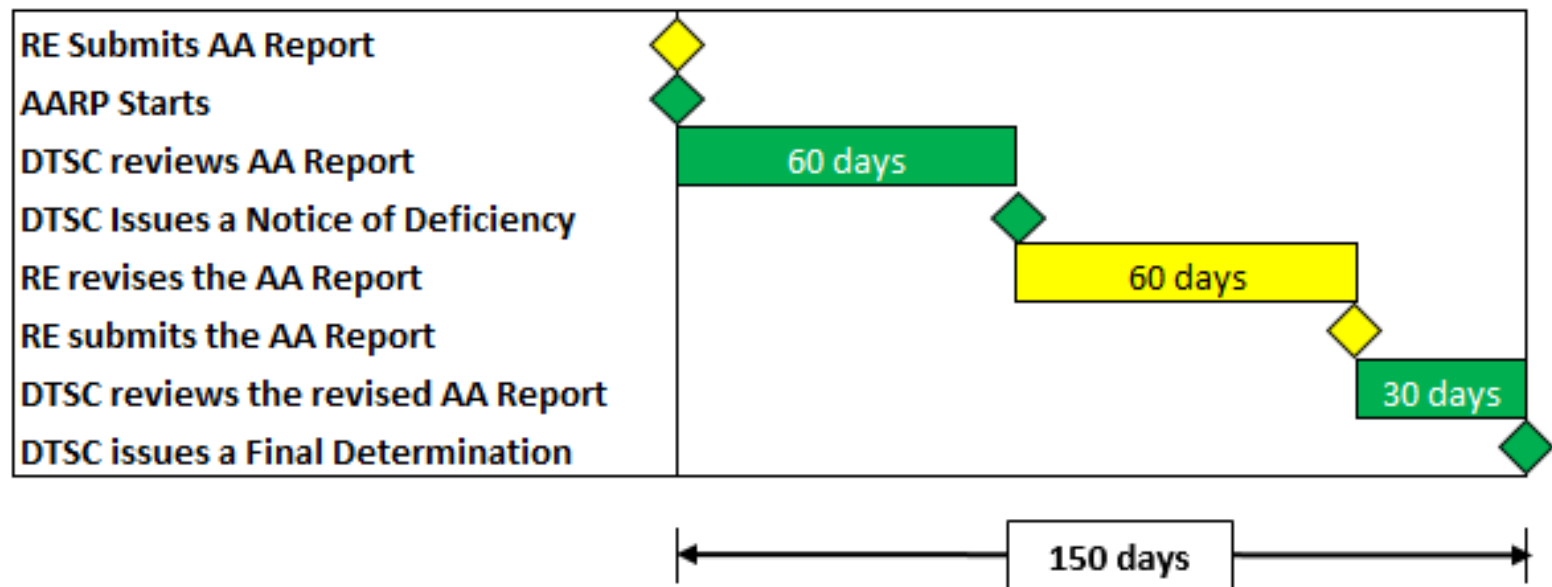
- Published in a scientifically peer reviewed report or other literature
- Published in a report of United States national Academies
- Published in a report by an international, federal, state, or local agency that implements laws governing chemicals
- Conducted developed submitted, prepared for, or reviewed and accepted by an international, federal, state, or local agency for compliance or other regulatory purposes; and

(B)

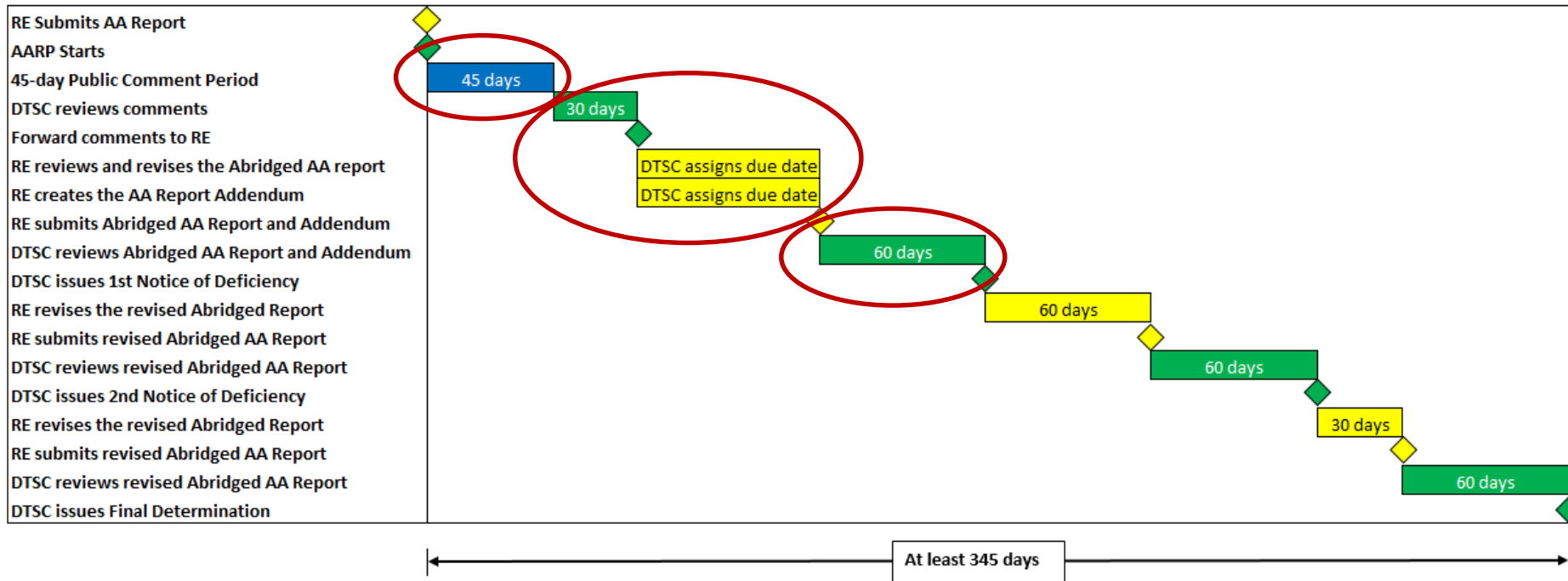
The study design was appropriate to the hypothesis being tested, and sufficient to support the propositions for which the study is presented to the department.



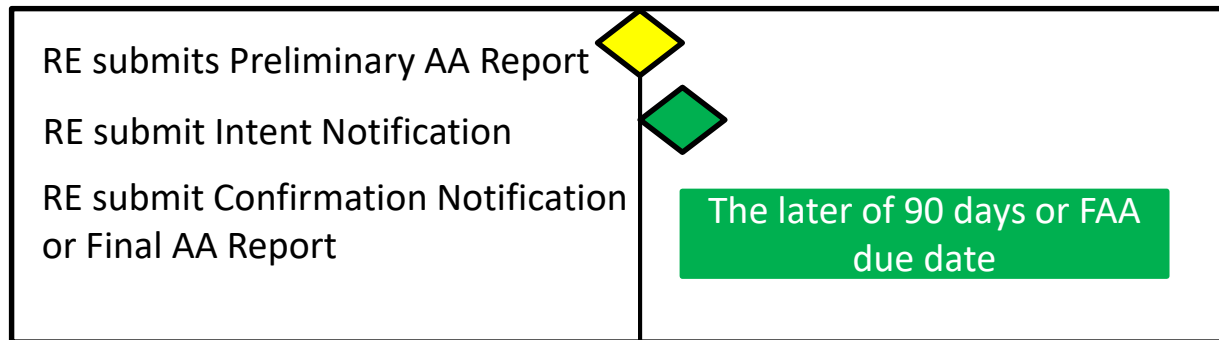
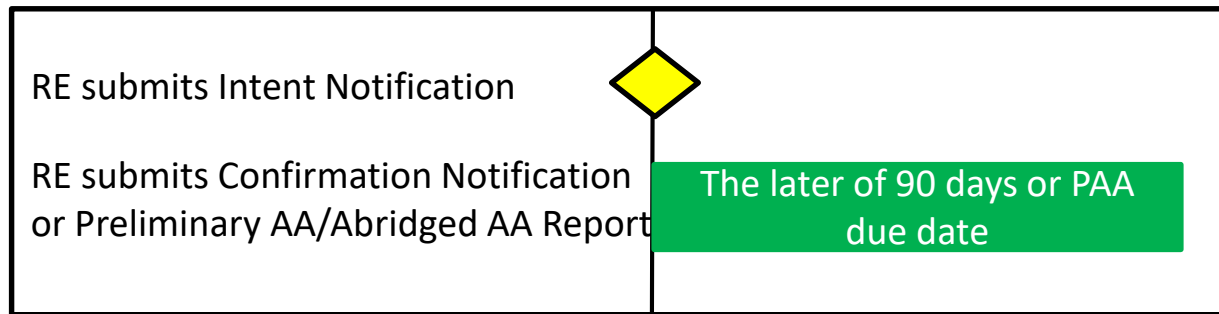
Preliminary AA Report Review Timeline



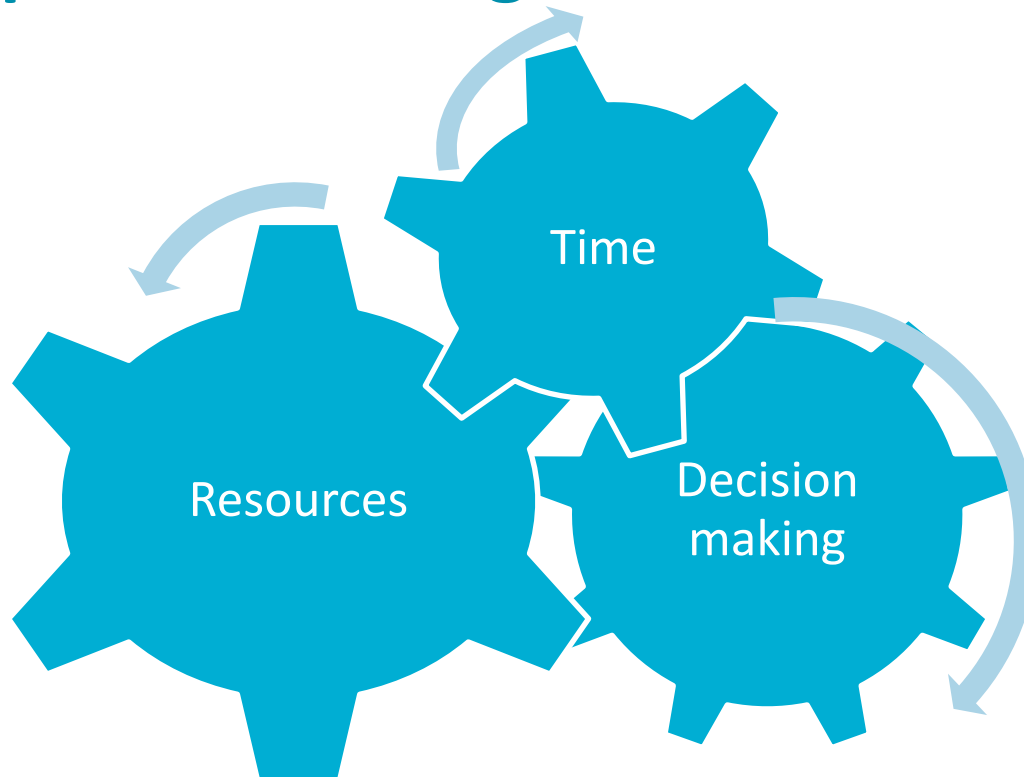
Abridged AA Report Review Timeline



Removal/Replacement Notification Timeline



Anticipated Challenges

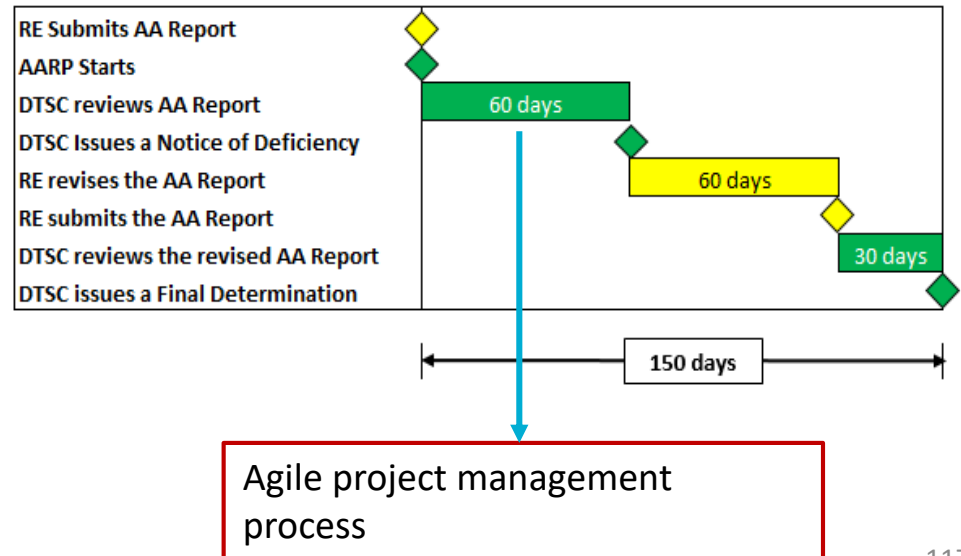


Challenge - Time

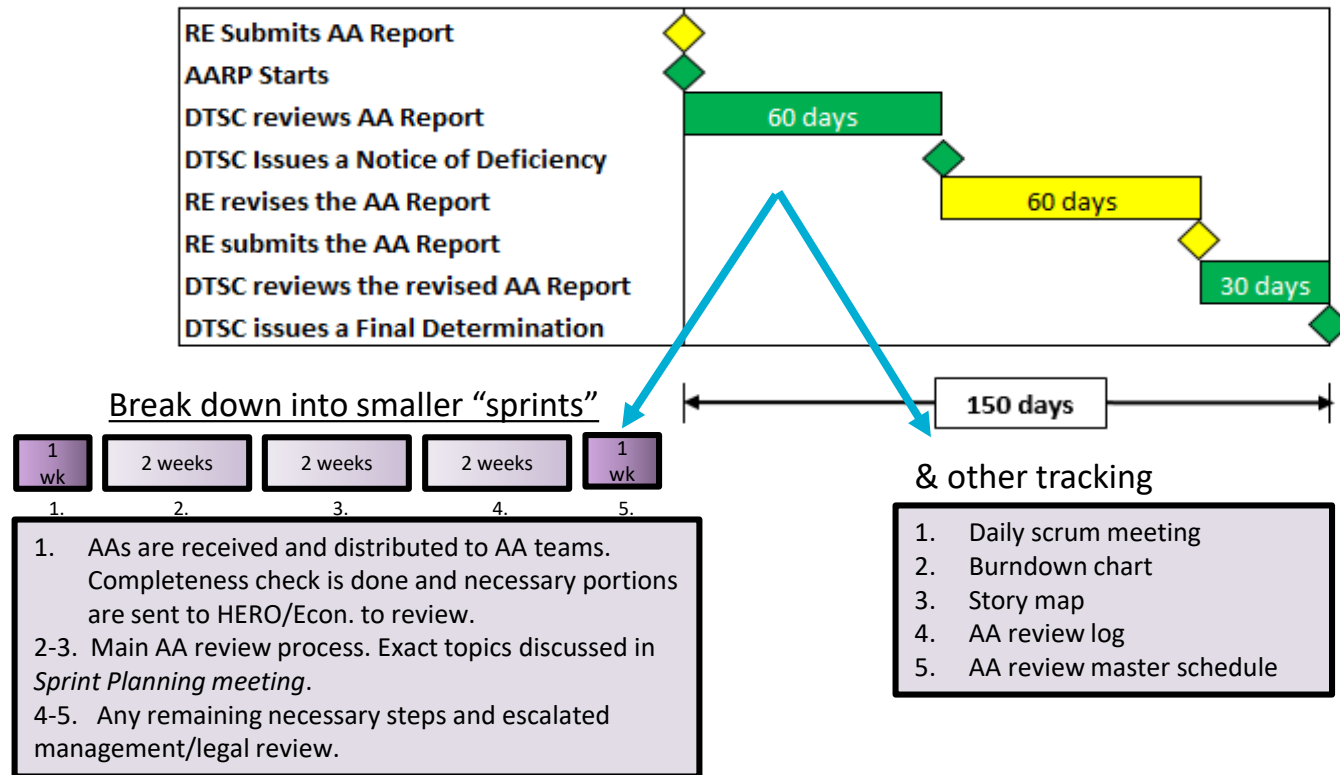
- Short turnaround time for review (typically 60 days)
- Uncertain timeline and workflow

Work to date

- Internal AA review process
- Agile project management
- CalSAFER backend test
- Trade secret protection



Agile Process

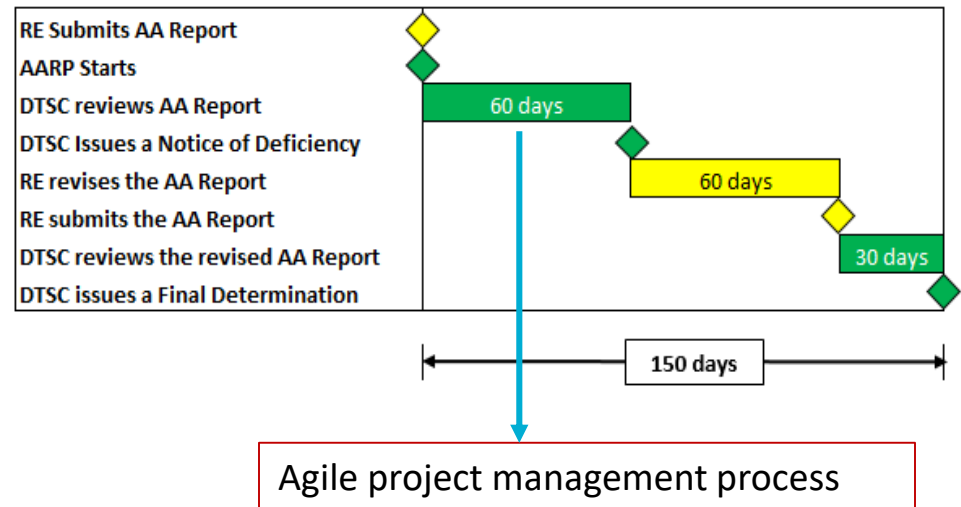


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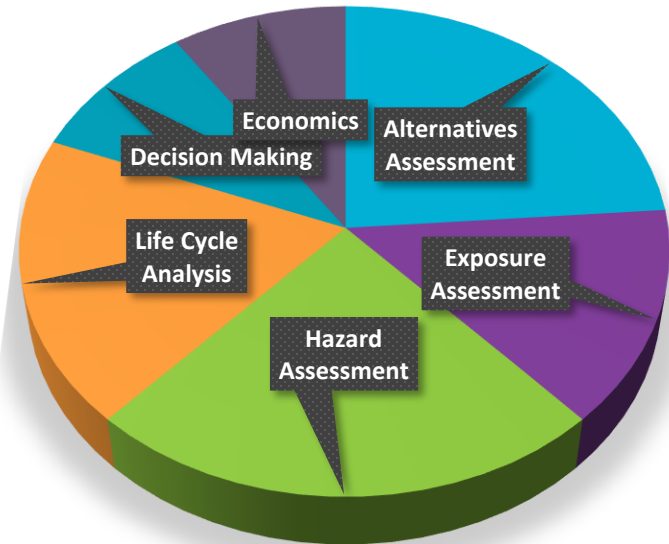


Challenge - Resources

- Comprehensive scope
- Untraditional multidisciplinary skill sets
- First time to review SCP AA Reports
- Small team and expertise gap

Work to date

- New hiring and recruitment
- Technical and process training and coordination
- Research references library
- Mock up AA reports review



Challenge – Decision making

- Value-based decision making involved
- Different scenarios and inconsistent quality expected

Work to date

- Stakeholder outreach and engagement
- Completeness and technical review checklists
- AA Response Strategy Team



Inviting Inputs from GRSP Members

- What methodologies, approaches, or strategies would the Panel recommend for a rapid review of an AA, while ensuring sound decision-making from the Department?
- Are there critical pieces of the Preliminary AA, Abridged AA, or Final AA Reports that the Panel would recommend focusing on reviewing, according to the review criteria in the SCP regulations?
- What should the Department look for to ensure AAs aren't being used to excuse the continued use of a Chemical of Concern?
- In the absence of minimum data standards, what are key elements that could be used for initial screening to judge the quality of an AA?





Tips and Tricks for Review of AAs

Presented at the DTSC Green Ribbon SCIENCE Panel Meeting

April 24, 2019

Margaret H. Whittaker
ToxServices LLC



Department of Toxic Substances Control



CalEPA

AA Review Process: Overarching Goals

- Goal of the AA review process should be the performance of credible, consistent, and efficient AA reviews
 - Each priority product type will have unique challenges and use different approaches to identify safer alternatives
 - Chap 11 of the AA Guide clearly instructs Responsible Parties (RPs) to assess their AA for reliability, validity, and plausibility
- First Tip: A good AA review requires understanding of the product:
 - Do your background research before starting the AA review!
 - Understand the product category in and out
 - Understand the 5Ws (and 1H) relating to the chemical of concern being used in that product type.



Alternatives
Analysis Guide
Version 1.0

DEPARTMENT OF TOXIC SUBSTANCES CONTROL
SAFER PRODUCTS AND WORKPLACES PROGRAM
June 2017

Department AA Review Criteria (22 CCR section 69505.9(a))

In reviewing AA Reports and Alternate Process Work Plans for conformance with the substantive and administrative requirements, the Department will consider:

- (1) Whether the AA Report or Alternate Process AA Work Plan was submitted on a timely basis;
- (2) Whether, and to what extent, the responsible entity considered and addressed all applicable provisions pertaining to the preparation and submittal of an AA Report or Alternate Process AA Work Plan, whichever is applicable;
- (3) Whether, and to what extent, the responsible entity demonstrated that the conclusions of the AA were based on reliable information, when applicable.



AA Review Process: Critical to Understand Frameworks, Test Methods

- Staff reviewing each part of the AA should have training in specific part of AA being assessed:
 - GHS hazard classification
 - Exposure assessment
 - Economic considerations
 - Performance models
- An AA reviewer needs to know how to identify reliable and appropriate test methods, hazard frameworks, exposure models
 - You will learn a lot by reviewing submissions. The RPs are the experts in their product type, but they won't be expert at CHA, LCA, or Economics
 - *Ask for full copies of test reports, chemical hazard assessments, and cited publications that they are relying up to justifying conclusions.*



Selection of Safer Alternatives: Evaluation of Sufficiency of Selection Framework

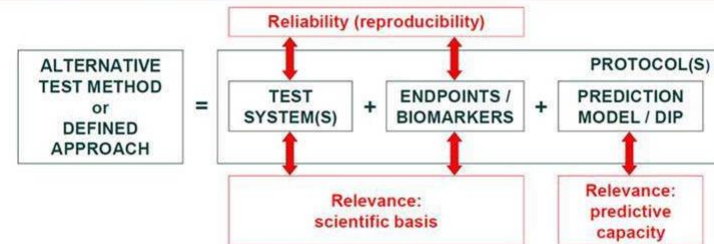
- Ensure that the individuals performing the AA are qualified to perform an AA!
- It is critical that hazard frameworks, test protocols, and test methods used to classify hazards as well as measure and assessment exposure be reliable and be sufficiently robust
 - OECD Test Guidelines should be followed
 - <http://www.oecd.org/env/ehs/testing/oecdguidelinesforthetestingofchemicals.htm>
 - For exposure modeling, AAs should completely document exposure equations and calculations



Selection of Safer Alternatives: Evaluation of Sufficiency of Selection Framework

- Test methods and frameworks should undergo external validation following something similar to [OECH Guideline 34](#)

Principles and criteria for validation (in a regulatory context)



More-specific definition of validation:

“... to establish the scientific basis and reproducibility of a test system and of the endpoints measured, and the predictive capacity of an associated prediction model”

Worth and Balls (2001), ATLA 29, 135-143



Resources

On-Going Work Groups and Trainings

- BizNGO Hazard Assessment in Decision-making Working Group
 - *Next call will be held on Tuesday 5/21 at 12 pm ET.*
 - *Topic: Endocrine Activity and the SIN List, Guest Presenter: Anna Lenquist, ChemSec*
 - *Email Shari Franjevic to shari@cleanproduction.org*

Training

- SOT Related Symposium: April 30, 2019: Intersection of Chemistry and Toxicology in the 21st Century
 - *In-Person and Video Webcast:*
<http://www.toxicology.org/groups/rc/ncac/events.asp>
 - PCRM's Two Day Workshop NAMs for Use in Regulatory Application (NURA) training, May 21-22, 2019 in Gaithersburg, Md.
 - *In-Person and Video Webcast:* <https://www.pcrm.org/ethical-science/animal-testing-and-alternatives/nura/modern-science>
 - GreenScreen Advanced Topics Course
- [GreenScreen Advanced Topics Course:](#) [Register](#) by 4/26/19.
- Authorized GreenScreen Practitioner Program®. [Apply](#) by 4/19/19.



Data Quality: IBT Test Data

- We often find many citations to Industrial Bio-Test Laboratories studies (many conclude the test substance is “negative” for the endpoint assessed, such as mutagenicity)
- It is important to remember the IBT studies that are suspect and OECD guidelines regarding their use.
- Here is the wording my staff and I use and a cite to the OECD guidance:
 - *A number of Industrial Bio-Test Laboratories (IBT) acute toxicity and irritation studies [CITE STUDY TYPE] are cited in this report. In the 1970's, IBT conducted 40% of the toxicology testing performed in the United States until the laboratory was shut down in 1978. In 1976, FDA uncovered widespread fraud at IBT during an audit, and implemented Good Laboratory Practices (GLP) regulations in 1979 to combat such fraud. IBT study types identified as potentially problematic were classified as “non-acute” studies, and included sub-acute, subchronic, carcinogenicity, reproductive toxicity (including teratogenicity), genotoxicity, and neurotoxicity (OECD, 2005). None of these problematic study types are cited in this risk assessment report. Klimisch scores reported by [SOURCE] are reported for each IBT study cited in this report.*
- **Reference:** OECD (Organisation for Economic Co-Operation and Development). 2005. Manual for the Investigation of HPV Chemicals. Chapter 3: Data Evaluation. Section 3.1 Guidance for Determining the Quality of Data for the SIDS Dossiers: (Reliability, Relevance, and Adequacy).
<http://www.oecd.org/chemicalsafety/risk-assessment/49191960.pdf>



THANK YOU

mwhittaker@toxservices.com – 202-429-8787



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